

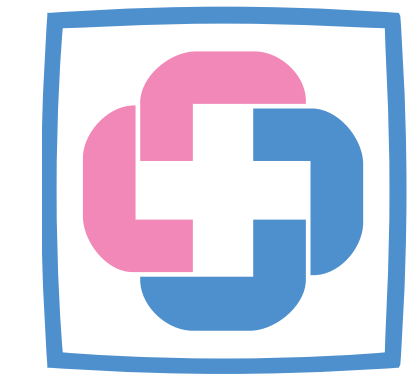


Streamlining the Process of Recording Storage Temperature of Investigational Products (IP)

Stored in KK Research Centre (KKRC) at Room Temperature

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INTRODUCTION

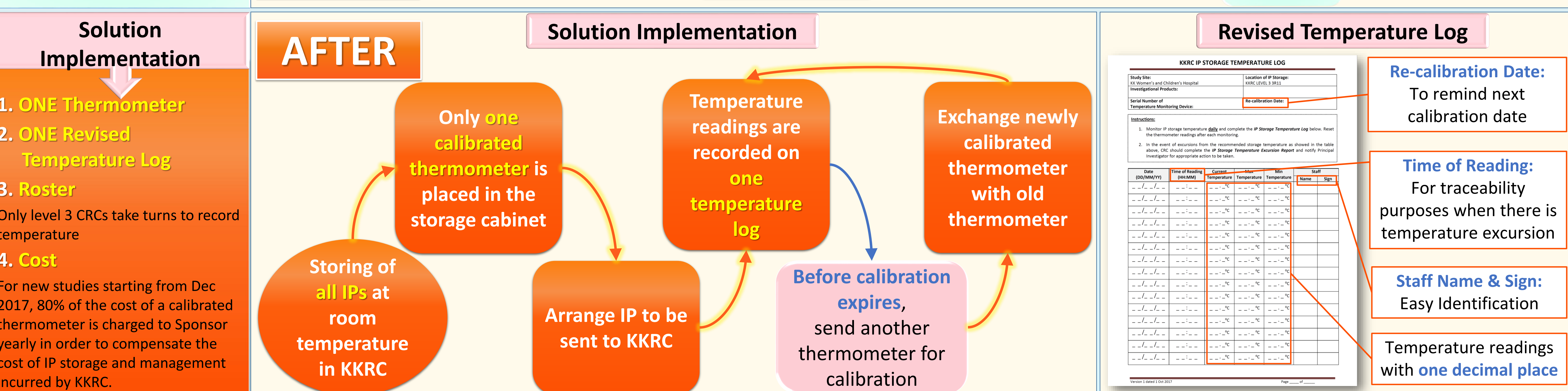
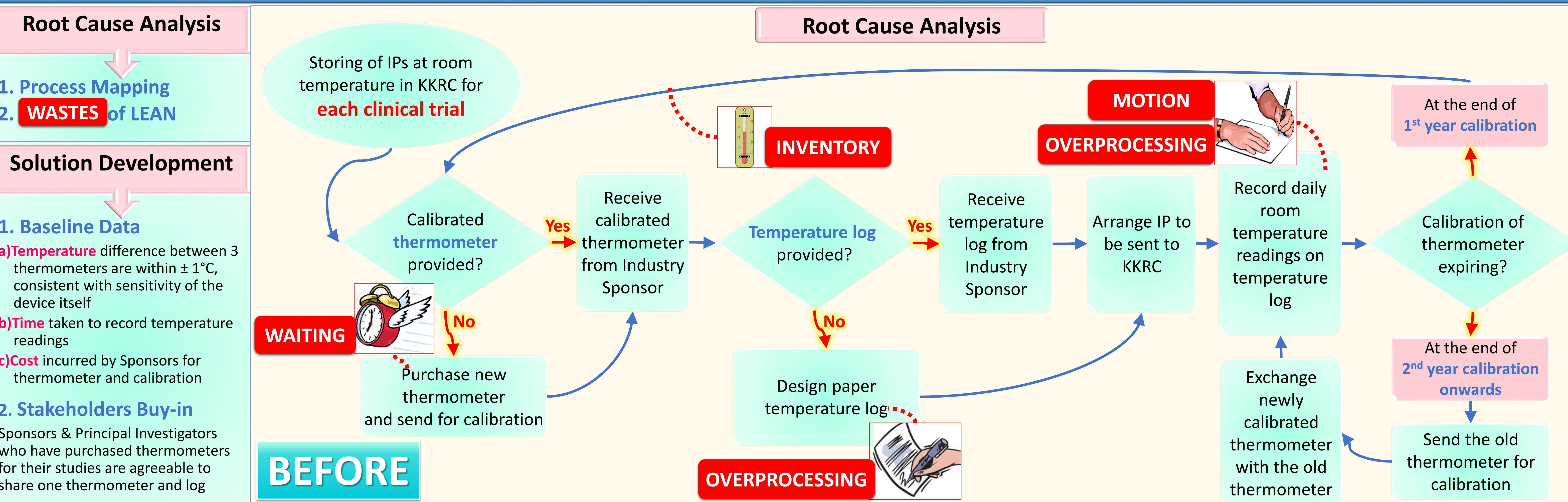
An **Investigational Product (IP)** is defined as a therapeutic product/ medicinal product or a placebo that is to be tested or used as a reference in a clinical trial. Monitoring of IP storage temperature is crucial in IP management, according to International Council for Harmonisation (ICH) GCP E6 R2.

As of August 2017, **five different IPs** are stored at room temperature in a storage cabinet at KKRC level 3. Daily room temperature readings are recorded by **four Clinical Research Coordinators (CRC)** from **level 3 and 4** using **three thermometers** placed in the **same storage cabinet**. The purchase of calibrated thermometers takes about 2 to 16 weeks to process, which results in delaying of IP shipment and study start-up. Each CRCs record temperature readings of respective thermometers using **paper temperature logs of various format**, that caused inconsistencies, redundancies and wastage of man hours in the workflow.

OBJECTIVES

To **reduce the number of man hours** needed to record storage temperature of IPs stored in KKRC at room temperature.

METHODOLOGY



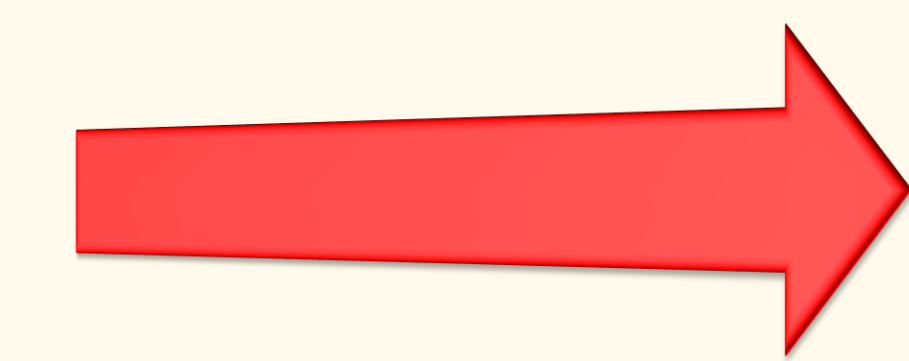
RESULTS & DISCUSSIONS

Shared Thermometer & Temperature Log

BEFORE



Only **ONE** thermometer is used to record room temperature readings



Only **ONE** temperature log is used to record room temperature readings

AFTER



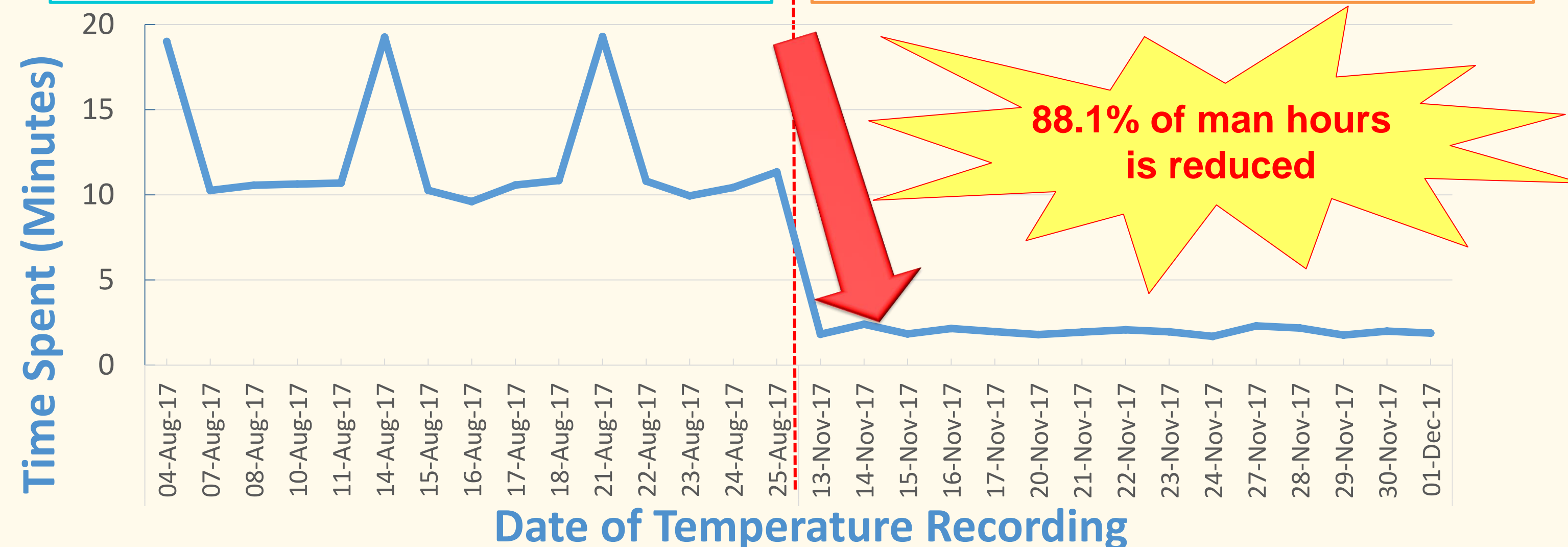
Total Time Spent in Recording Temperature

BEFORE

Every day, 4 CRCs from level 3 and 4 record 15 days of readings & spent a **Total Time: 249.64 mins = 4.16 hours** using **3 thermometers** and **4 logs**

AFTER

Every day, 4 CRCs from level 3 take turns to record 15 days of readings & spent a **Total Time: 29.72 mins** using **1 thermometer** and **1 log**



CONCLUSION

One thermometer and **one revised temperature log** are shared in order to streamline the storage temperature recording for **all IPs** stored in KKRC at room temperature. With that, the total **time** spent to record room temperature readings for all IPs is reduced. Moreover, there is no need to purchase new thermometers for other IPs, which eliminates waiting time to arrange for IP shipment and thus preventing delay in starting up a study. This reduces wastes and redundancies in our workflow.

For sustainability, all new studies that require to store IPs at room temperature in KKRC are required to include the **cost** for IP storage and temperature monitoring in the study budget, which will be incurred by KKRC in providing a calibrated thermometer for all IPs.