To Improve Current Workflow to Enhance Protection of Trial Data Confidentiality at KK Research Centre

Vivien FU Yan Wei, Sonny LIM, LIAW Chiew Suan, LIU Juan, WONG Anng Anng, Yin Aye Moe, KK Women's and Children's Hospital

1. INTRODUCTION

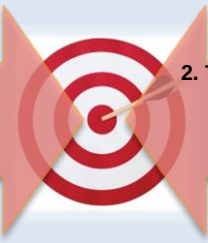
Maintaining trial data confidentiality is critical during the conduct of clinical research. The research team is obligated to meet the requirements of applicable regulations, such as Clinical Trial Regulations, Personal Data Protection Act 2012 and Singapore Guidelines for Good Clinical Practice (SG-GCP). The unintended release of confidential trial data will result in possible personal or economic damage to the study participants and sponsor.

In order to reduce the risk in our trial data management, we have improved our current workflow to further enhance protection of trial data confidentiality at KK Research Centre (KKRC).

2. AIMS

Our stakeholders are:
Investigators, Collaborators, Study Team Members, Sponsor Representatives, Clinical Research Organization Representatives, KKH Internal Staffs

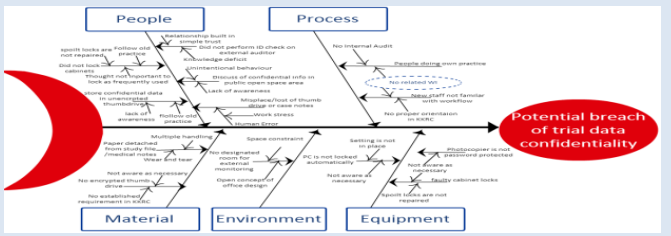
1. To achieve 100% no breach of trial data confidentiality



2. To significantly increase our stakeholder's confidence on our capability in trial data protection

3. METHODOLOGY

We analyzed root cause for potential breach of trial data confidentiality using Fish Bone Diagram.



We conducted Gap Analysis for the current workflow following three steps:

1. Identified gaps in current workflow.
2. Analysed what causes the gaps.
3. Brainstormed for possible solutions.

Current workflow	Gap in current workflow	What cause gap in current workflow	Solution to address gap in current workflow
Clinical Trial Agreement and Non-disclosure Agreement signed by sponsor prior to trial commencement.	No gaps identified.	Nil	Nil
Task Delegation Log and study contact list of personnel involved in the study are filed in the Investigator Site File. Remarks: Only authorized personnel have the access to the trial data. Authorized personnel who have access to the trial data include the members of the study team. Their names can be verified from the Task Delegation Log and study contact list.	No proper verification of identity of external /visitors when they entering KKRC	No established workflow on proper verification.	1.To develop enhanced workflow in addition to current workflow: a) Sponsor, rather than the Clinical Research Organization (CRO) should send an email containing the full name and ID (NRIC, employment pass/work permit or passport etc. where appropriate) to the site introducing the newly assigned Clinical Research Associate CRA(s) who will have full access to our study files. Any changes in sponsor representative(s) or CRA(s) should be updated in writing to site immediately. It is recommended that sponsor representative to introduce any newly appointed CRA(s) to the site in a face-to-face meeting. Any persons not listed in the authorized personnel list will NOT have any access to our clinical trial information. b) CRC must ensure proper verification of identity of personnel before allowing them access to sensitive/confidential trial information. For the initial verification, KKRC CRC must verify the CRA accessing the study files using documentary proof for full name, ID and company employment status (e.g. CRO staff pass). CRC need to make copies of all documents submitted by CRA for filing. c) Random audit to confirm the identity of the authorized CRA personnel will be conducted bi-monthly. 2. To develop new Work Instruction (WI) "Trial data security and confidentiality" and include the above enhanced workflow. 3. To develop orientation checklist and include the above workflow for new staff.
Timely update of study contact list and Task Delegation Log.	The contact list and Task Delegation Log are not updated in timely manner.	Some study team members left the organization without informing CRC.	CRCs to highlight the requirement during the Site Initiate Meeting.
Monitors having access to trial data and source data to update their visits in the Monitoring Visit Log.	1. At the end of each study monitoring visit, not all study coordinator will check and acknowledge the entry in the Monitoring Visit Log. 2. Sometimes monitors are left alone in the office during the monitoring visit.	There is no written instruction that study coordinators must acknowledge each monitoring entry after each visit and do not leave the monitors alone in the office during monitoring visit.	1. To develop enhanced workflow in addition to current workflow: a) For continuous monitoring, the CRA must sign the monitoring log each time he/she access the study files/medical notes and each entry must be acknowledged by the site staff. Any personnel who have accessed the site file/medical notes but subsequently refused to sign the monitoring log should be reported immediately. b) CRCs should host monitoring visits in the designated monitoring room. c) External monitors must not be left unaccompanied in the office during the monitoring visits. d) No discussion of confidential data openly in the office area. 2. To develop new Work Instruction (WI) "Trial data security and confidentiality" and include the above workflow. 3.To develop trial data protection checklist and include the above workflow for new staff.
Different identification code given to each user to access the electronic data collection (EDC)	1. Not all computers and laptops are logged off or shut down when they are not in use. 2. Non-encrypted thumb drive was used for transfer of electronic trial data.	Staff lack of awareness.	1. To develop enhanced workflow in addition to current workflow: a) All computers and laptops should be logged off or shut down after office hour. b) If transfer of electronic trial data is required, CRCs should use encrypted portable device with password protection. 2. To develop new Work Instruction (WI) "Trial data security and confidentiality" and include the above workflow. 3. To develop trial data protection checklist and include the above workflow for new staff.
All computers and laptops are password protected	1. KKRC photocopier was not password protected. 2. Study coordinators did not standby when study monitor doing the photocopying. 3. Printouts are accessible by all KKRC staff.	1. The old machine doesn't have this function. 2. No established workflow.	1. We replaced the photocopier which is password protected. 2. To develop enhanced workflow in addition to current workflow: a) KKRC photocopier is password protected and only accessible by authorized personnel. b) Photocopying of documents should be done by study coordinator in-charge. c) CRCs should shred those unwanted confidential documents instead of discard them into the dust bin directly. d) CRCs should pick up printout immediately when printing confidential trial documents. 3. To develop new Work Instruction (WI) "Trial data security and confidentiality" and include the above workflow. 4. To develop trial data protection checklist and include the above workflow for new staff.
Confidential trial data are stored in cabinets allocated to designate CRC	Not all cabinets are locked after usage.	1. Some locks are faulty. 2. Staff lack of vigilance.	1. Faulty locks are repaired. 2. CRCs are reminded that hardcopy of confidential trial data must be kept in designated cabinets under lock and key at all times to limit access. 3. To conduct random check to ensure compliance.

From there, we conceptualised and implemented the enhanced new workflow.

During implementation, we conducted training to our staff for better adherence, we also developed work instruction and trial data protection checklist to standardise the practice.

After implementation, we conducted survey to evaluate our stakeholders' confidence level and to collect feedback for further improvements.

In the survey form, we introduce our existing workflow and the enhanced workflow to our stakeholders for comparison first, then we ask them three questions.

Survey Form for Process Improvement Project
KK Research Centre

Project title: To improve the current workflow in protecting data confidentiality at KK Research Centre
Project Period: Jul 2013-Jan 2014
Date of survey: I__I__I-I__I__I-I__I__I__I__I (dd: mm: yyyy)

Introduction:
Since the initiation of the project, KKRC has revised our workflow on data security and confidentiality. Please refer to Annex A to compare the existing workflow and improved workflow to protect data confidentiality.

Related Work Instruction "Data Security and Confidentiality" was developed and training of the workflow to all staff had been conducted in Oct 13.

This survey form is completed by:

- ☐ Investigator
- ☐ Clinical Research Coordinator
- ☐ Clinical Research Associate or representative from CRO/Sponsor
- ☐ Others, please specify_____ (e.g. DDMS)

1. Does your confident level increase with the improved workflow in protecting data confidentiality? Please tick your rating below:
   - ☐ Significantly decrease
   - ☐ Slightly decrease
   - ☐ Neutral
   - ☐ Slightly increase
   - ☐ Significantly increase
2. PDPA (Personal Data Protection Act) will be come into full force in Jul 2014; do you think that the additional steps (refer to Annex A) are sufficient to help KKRC coordinators for better adherence to the Act? Yes ☐ No ☐
3. If the answer is "No" for question 2, do you have any suggestion for our improvement?

Name: _____ (Optional)

Thank you for taking the time to fill up this survey form.

Trial Data Protection Checklist (KK Research Centre)

	Items	Check √ If Done	CRC Signed & Date	Verified & assessed by RO or designated CRC
Prior to commencement of clinical trial	1)Clinical Trial Agreement and Non-disclosure Agreement signed by sponsor.	☐		
	2)Contact list and Task Delegation Log of personnel involved in the study are filed in the Investigator Site File.			
	3)Sponsor to identify, inform and introduce assigned Clinical Research Associate (CRA) from appointed Clinical Research Organization (CRO) preferably in a face-to-face meeting.			
During execution of clinical trial	1)Timely update of study contact list and Task Delegation Log.			
	2)Monitors having access to trial data and source data to update their visits in the Monitoring Visit Log.			
	3)Different identification code given to each user to access the electronic data collection (EDC).			
	4)All computers and laptops are password protected.			
	5)All computers and laptops should be logged off or shut down after office hour.			
	6)Confidential trial data are stored in cabinets allocated to the Clinical Research Coordinator (CRC) under lock and key.			
	7)Sponsor to update any change in assigned CRA from appointed CRO preferably in a face-to-face meeting.			
	8)KKRC CRC to verify the CRA accessing study materials during monitoring visit using documentary proof.			
	9)For continuous monitoring, the CRA must sign the monitoring log each time he/she access the study files/medical notes and each entry must be acknowledged by the site staff. Any personnel who have accessed the site file/medical notes but subsequently refused to sign the monitoring log should be reported immediately.	☐		
	10)Random audit will be performed bi-monthly for CRC compliance.	☐		
	11)A designated place/room catered for monitoring purpose.	☐		
	12)External monitors must not be left unaccompanied in the office during the monitoring visits.	☐		
	13)No discussion of confidential data openly in the office area.	☐		
	14)If transfer of electronic trial data is required, CRCs should use encrypted portable device with password protection.	☐		
	15)Photocopier is password protected and only accessible by authorized personnel.	☐		
	16)Photocopying of documents should be done by study coordinator in-charge	☐		
	17)CRCs should shred those unwanted confidential documents instead of discard them into the dust bin directly.	☐		
	18)CRCs should pick up printout immediately when printing confidential trial documents.	☐		
	19)No visitors should be left alone in office at all time.	☐		

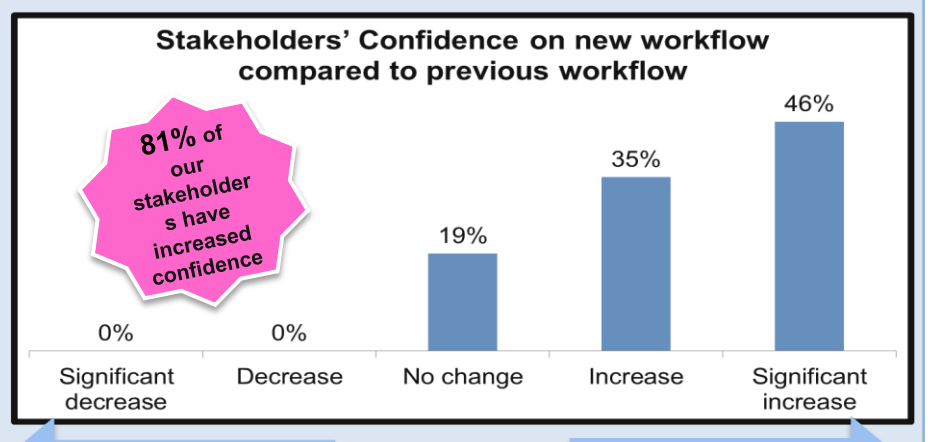
We use "Trial Data Protection Checklist" to conduct training to staff.

4. RESULTS

1. After implementation of the new workflow,

NO incident of potential breach of trial data confidentiality reported.

2. We received 72 completed survey forms from our stakeholders, 81% had increased confidence on our capability in trial data protection.



3. We also received some constructive feedback (Question #3, in the survey form) through this survey which help us further improve our workflow. For example, development of house rules for the Clinical Research Associates (CRAs) to follow while they are conducting monitoring activities at our premises.

5. CONCLUSION & FUTURE WORK

The new workflow has helped our research coordinators to better protect trial data confidentiality in accordance to SG-GCP and applicable regulatory requirements. It has also helped to improve our overall risk management in trial data protection at KKRC.

To maintain sustainability, training and education will be provided regularly. Audit on compliance to the new workflow will be conducted. We will also periodically review and update our work instructions and house rules to ensure they are in line with the latest relevant requirements.