Monitoring Framework at KK Women's and Children's Hospital

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Vivien FU Yan Wei, Sonny LIM, LIU Juan
KK Women's and Children's Hospital

Introduction

Monitoring is a function that is critical to manage risks involved in the conduct of clinical trials. As stated in the Singapore Guideline for Good Clinical Practice (SG-GCP), the purposes of monitoring are to verify that:

- The rights and well-being of human subjects are protected.
- The reported trial data are accurate, complete, and verifiable from source documents.
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

For Industrial-Sponsored Trials, the sponsors establish a thorough monitoring system. For Investigators-Initiated Trials (IITs), the function should be performed by the Institution/Investigator. However, previously there were no monitoring activities for KKH IITs requiring Clinical Trial Certificate (CTC), except for those carried out by SingHealth Clinical Trial Compliance Unit (CTCU). In order to close this gap, KKH implemented a risk-based monitoring framework which focuses on investigator initiated drug trials not monitored by CTCU.

Methodology

There were 5 phases in the development of the monitoring framework:

Forming of work group

Firstly, a work group consisting of KK Research Centre (KKRC) Head of Department, Assistant Manager, and Clinical Research Coordinators (CRC) was formed in Sep 2012. Numerous meetings have been conducted to brainstorm and analyse the key topics of the monitoring framework.

Learning from the best practice

KKRC team visited CTCU to gather feedback and learn from their best practice.

Developing the two-stage risk-based monitoring framework and training of monitor

After careful evaluation of all inputs, KKRC developed a two-stage risk-based monitoring framework. KKRC also sent the experienced CRCs for relevant trainings to become Trial Monitor.

Seeking the Medical board's approval of implementation

In January 2013, Medical Board approved the implementation of the monitoring framework.

Striving for continuous improvement

This is an on-going project; KKRC is continuing working on the improvement of the monitoring framework to enhance KKH overall trial quality.

Result

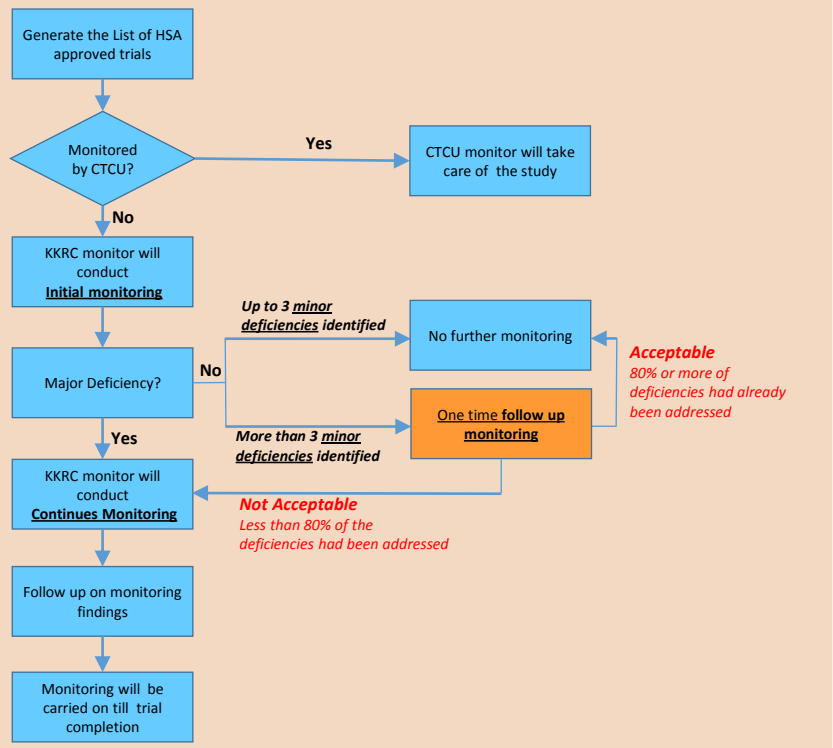
What have we achieved ?

To date, KKRC has completed monitoring of 5 IITs.

I. The results of the monitoring have been highlighted to the medical board for further improvements of KKH clinical trials.

II. In order to standardise the monitoring process, KKRC has also developed a related hospital Policy and Procedure as well as Work Instructions for the department.

Monitoring Framework Workflow



III. To maintain sustainability, KKRC has set a Key Performance Indicator (KPI) on monitoring to ensure all IITs requiring CTCs are 100% monitored.

Conclusion

KKH has benefited from the risk-based monitoring framework by meeting SG-GCP and the applicable regulatory requirements, as well as better managing the risks involved in the clinical trial.

References

1. Singapore Guideline for Good Clinical Practice
2. KKH Policy & Procedure Manual 81010-0037, titled: KKH Monitoring Framework