Development of New Trial Protocol Development Process Chart using Quality by Design method

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Purpose: In recent clinical trials, it is very important to ensure data quality and subject protection in the trial by building up a quality management system (QMS) or applying a quality control plan (QMP). The quality and risk based approach of a clinical trial is known to quality by design approach (QbD). In QbD implementation process during protocol planning phase is consisted from many steps and there are many considerations in each steps, but usually, these steps or milestones will be implicit and remain unclear until the trial initiation, in spite of trial monitoring with CtQ (Critical to Quality) factors. In this research, we developed the new trial protocol development process chart by using QbD method to optimize protecting subjects and securing data quality during the clinical trial. This study is being implemented as outsourcing project by the Japan Medical Association.

Methods: We divided trial planning phase into steps considering intermediate products of trial protocol and considerations which have relationship with a quality control indicator essential to the protocol or related to clinical practice. Finally, we summarized trial planning phase into 4 phase which include almost 20 related steps with 5 outputs.

Results /Discussions: We developed a new trial protocol development process chart which is essential to practicing the QbD approach. There are many considerations during protocol development phase, but we have to achieve the quality required for trial. Using this process chart, it will be helpful to implement quality measures and achieve the required quality in a practical way.