Survey questionnaire

1. What is the type of your company?  
   - Pharmaceutical company  
   - Multinational pharma  
   - Contract Research Organization (CRO)  
   - Other (Specify) ____________________________________________________________________________

2. How many clinical trials (phases I to III) did your company conduct or involve through outsourcing in South Korea in 2018?  
   - 1 to 5  
   - 6 to 10  
   - 11 to 20  
   - 21 to 30  
   - 31 to 50  
   - 50 to 100  
   - More than 100  
   - N/A

3. How many personnel are involved in the clinical trial activities (operation, DM, statistic, IT, medical director, etc.) at your company?  
   - Up to 10  
   - 11 to 20  
   - 21 to 30  
   - 31 to 50  
   - 50 to 100  
   - More than 100  
   - N/A

4. Does your company have personnel who are involved in the following tasks to manage the quality of clinical trials? (Select all that apply, regardless of operating quality assurance department, choose any tasks partially involved)  
   - System audit  
   - Individual trial audit  
   - Non-compliance management  
   - Issue/CAPA management  
   - SOP management  
   - Training management  
   - Risk management  
   - Productivity  
   - Cost effectiveness  
   - Systemic vendor oversight and management  
   - Increasing training opportunity  
   - Systemic non-compliance management  
   - Improving process through consultation  
   - Other Systems ___________________________________________________________

5. Personnel and department designated to quality management  
   - Quality management department  
   - Other (Specify) ____________________________________________________________

6. Choose the statement that best describes your company’s reporting structure of the quality control personnel. (If there are no personnel provided earlier)  
   - No, and we plan to recruit  
   - No, but in preparation  
   - Yes  
   - Not outsourcing  
   - N/A

7. If your company has been using risk-based monitoring (RBM), in what perspective do you think RBM is effective? (If currently not undertaking risk-based monitoring, select N/A)  
   - Enhancing quality control of individual clinical trial  
   - Improving process through consultation  
   - Remediation of non-compliance  
   - Other (Specify) ____________________________________________________________

8. To what extent has your company been using risk-based monitoring? (If currently not undertaking risk-based monitoring, select N/A)  
   - Yes (Enter the number of personnel)  
   - Yes, but only for some parts  
   - No, but in preparation  
   - N/A

9. If you answered outsourcing to Q8, what is the main reason for outsourcing? (If not outsourcing tasks, select N/A)  
   - Lack of experts in my company  
   - Not outsourcing  
   - System audit  
   - Individual trial audit  
   - Non-compliance management  
   - Issue/CAPA management  
   - SOP management  
   - Training management  
   - Computerized system validation management  
   - Improving process through consultation  
   - Other (Specify) ____________________________________________________________

10. If your company has undertaken risk assessment before starting a clinical trial?  
   - Yes  
   - No, but in preparation  
   - N/A

11. Does your company undertake risk assessment before starting a clinical trial?  
   - Yes  
   - No, but in preparation  
   - N/A

12. How many personnel are involved in the risk assessment task at your company? Please provide the best estimated value.  
   - 1 to 5  
   - 6 to 10  
   - 11 to 20  
   - 21 to 30  
   - 31 to 50  
   - 50 to 100  
   - More than 100  
   - N/A

13. To what system did your company implement risk assessment? If your company hasn’t implemented risk assessment yet, which system do you think should be prioritized for implementing risk assessment? Please select UP TO 2 systems.  
   - Monitoring system  
   - SOP management system  
   - CAPA management system  
   - Computerized system  
   - Issue/CAPA management  
   - System audit  
   - Individual trial audit  
   - Non-compliance management  
   - SOP management  
   - Training management  
   - Computerized system validation management  
   - Improving process through consultation  
   - Other Systems ________________________________________________________________

14. Has your company implemented risk-based monitoring (RBM)?  
   - Yes  
   - No, but in preparation  
   - N/A

15. Has your company implemented risk-based monitoring (RBM)?  
   - Yes  
   - No, but in preparation  
   - N/A

16. To what extent has your company been using risk-based monitoring? (If currently not undertaking risk-based monitoring, select N/A)  
   - Yes (Enter the number of personnel)  
   - Yes, but only for some parts  
   - No, but in preparation  
   - N/A

17. If your company has been using risk-based monitoring (RBM), in what perspective do you think RBM is effective? (If currently not undertaking risk-based monitoring, select N/A)  
   - Enhancing quality control of individual clinical trial  
   - Improving process through consultation  
   - Remediation of non-compliance  
   - Other (Specify) ____________________________________________________________

18. Please select the option that best describes your job.  
   - Clinical trials manager  
   - Clinical trials coordinator  
   - Site manager  
   - Investigator  
   - Study nurse  
   - Pharmacist  
   - Computer programmer  
   - Other (Specify) ____________________________________________________________

Once you complete this survey, you will be rewarded with Starbucks Gifticon. The reward will be sent to the email address you registered.

SUPPLEMENTARY MATERIAL

Survey of risk-based quality management and clinical trial operation status in South Korea

This survey is to examine the current quality management practices of pharmaceutical companies and contract research organizations (CROs) operating in South Korea. All information you share in this survey will be kept confidential. It will be used for statistical analysis. The results may be used and shared in a report to the project. Survey results (or risk-based quality management practices) may be shared with the questionnaire model built on ECL 2018 (Conducted under the Korea National Research Foundation Grant funded by the Korean Government (NRF-2018R1D1A6B02079723)).