ICPM 2018 (International Conference in Pharmaceutical Medicine)

Workshop 1

Innovations in clinical trials*

Chaired and written by Kazuya Iwamoto[1], Ingrid Klingmann[2]

Topics: Adaptive design in clinical trials
Patient involvement in protocol design
Risk-based monitoring approach in clinical trials

Speakers/Panelist: Akihiro Hirakawa[3]
Satoshi Saeki[4]
Pol Vandenbroucke[5]
Dominique Dubois[6]

1) The Japanese Association of Pharmaceutical Medicine, Japan
2) PharmaTrain Federation, Belgium
3) The University of Tokyo, Japan
4) Astellas Pharma Global Development, United States
5) Pfizer, United States
6) Physician Specialist in Pharmaceutical Medicine, Belgium

Objectives

Significant advances have been made in the design and execution of clinical trials in order to maximise their chances for success and reduce their costs. Advances such as adaptive designs focused on the needs and opportunities to innovate drug development, bringing increased efficiency and improved decision making, and ultimately increasing the likelihood of bringing beneficial therapies to market. Also involving the end-user of drug development, the patient, into the design selection process of clinical trials turns out to be an essential success factor as it helps clinical trialists to strengthen the trial's relevance and acceptance for the patient. During the execution phase, emphasis on risk management such as risk-based monitoring helps the study teams to focus their attention and activities on the areas of greatest need: patient safety and data quality.

This session was intended to provide expertise on current challenges, innovative improvement options and an update on expected methodological changes in clinical trials.

Learning Outcomes

At the end of this session the attendees will be able to:

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Color version: http://cont.o.oo7.jp/47_2/47_2contents_e.html

- Understand the concept of adaptive designs and how this will increase efficiency of clinical drug development.
- Recognize how relevant patient involvement in the protocol design phase is today and will be in future
- Learn about the key element of risk-based monitoring as proposed by ICH-GCP(R2) and TansCelerate BioPharma Inc. and understand how this is applied in clinical trials.

Outcomes

This session brought together these experts to address innovations and challenges in clinical trials from design to execution and to discuss where the clinical trial methodology will be heading towards in the near future.

During the session, Dr. Hirakawa explained the concept of adaptive designs. He also showed examples of adaptive designs used in the past in multiple therapeutic areas and how these use can increase efficiency of clinical drug development in the near future. Dr. Vandenbroucke emphasized the relevance of patient involvement in selection of protocol design, gave examples for successful patient engagement and asked us to recognize how relevant patient involvement in the protocol design phase will be in future. Finally, Mr. Saeki made a presentation on modern strategies for quality control in clinical trials by providing comprehensive instructions for handling the key elements of risk-based monitoring as proposed by ICH-GCP(R2) and TansCelerate BioPharma Inc., based on the results of a survey on how risk-based monitoring is applied.

After the experts' presentations, a panel discussion was held including the audience. During the discussion, Dr. Dominique Dubois clarified key points on innovations and challenges in clinical trials with these three speakers, followed by interesting discussions between the audience and the speakers about experiences with these innovative concepts.

Conclusion

This session dealt with the advancement of clinical trials from design and execution aspects. The audience as well as the speakers and chairs supported in principle the concepts of these advancements and were inspired by the discussions to apply these modern concepts in their own drug development environment.

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