ICPM 2018 (International Conference in Pharmaceutical Medicine)

Workshop 2

Ethics in medicines development*

Chaired and written by Chieko Kurihara [1], Sandor Kerpel-Fronius [2]

Presentations: Ethical issues in gene therapy
Alan Boyd [3]

Managing multi-professional and multi-disciplinary teams
Sandor Kerpel-Fronius [2]

Ethics Committees in Asia
Chieko Kuriahara [1]

Social and ethical problems in drug pricing
Greg Koski [4]

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Learning objectives

(1) To increase awareness of new, emerging ethical problems in medicines development, paying particular attention to the development of gene therapy.

(2) To contribute to the understanding of ethical questions connected to the cooperation of physicians and life scientists in multidisciplinary teams.

(3) To focus on potential regional differences in considering ethical questions with special emphasis on Asia.

(4) To understand ethical-social problems in the context of drug pricing

Outcomes

According to learning objectives set in advance, achievements of this workshop can be described as follows:

(1) To Critically appraise ethical issues related to the development of advanced therapies, particularly gene therapy related clinical research:

Alan Boyd showed that 2,597 gene therapy clinical trials have been conducted worldwide as of 2017 and

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

introduced 6 cases of product approvals to date. He pointed out unpredictable risks associated with gene therapy using a carrier vector to deliver the therapeutic gene into the patient's target cells. Meanwhile, regulatory viewpoints concerning manufacturing, safety and efficacy are not so much different from other kinds of products. Therefore, collaborative work among the team of various expertise is prerequisite for successful achievement. He also pointed out social risks in "gene editing", which enables genomic modifications in a wide variety of organisms and tissues, which is now technically possible to be applied in human embryo gene editing.

(2) To evaluate and manage ethical issues of multidisciplinary clinical trial teams:

Sandor Kerpel-Fronius demonstrated the historical process leading to the development of modern multi-professional-multidisciplinary clinical drug research teams. He led the Ethics Working Group to develop 2nd edition of the IFAPP International Ethics Framework for Pharmaceutical Physicians and Medicines Development Scientists, finalized in March 2018 [1]. He mentioned some relevant paragraphs of this Framework emphasizing that ethical recommendations should be continuously adjusted to the new challenges created by the advance of science, where multiprofessional team must share joint responsibility.

(3) To describe and evaluate specific ethical issues in the Asian region:

Chieko Kurihara gave a summary of the problems faced by Ethics Committees or Institutional Review Board (EC/IRBs) in Japan, South Korea and Taiwan, where big scandals lead to expansion of the scope of clinical research regulations. EC/IRBs of each country are making efforts to get international or domestic accreditation or certification to achieve credibility. She stressed that networking of accredited/certified EC/IRBs would provide reliable platform for the conduct of global clinical trials. Also she emphasized the importance of core ethical values to respect/protect dignity and well-being of research participants.

(4) Analyze and manage the consequences of ethical-social issues in drug pricing

Greg Koski provoked a discussion articulating challenging situations where the regulators and the society require more and more evidence of safety and efficacy which leads to larger amount of money and time invested into product development. He posed a fundamental question whether health is human right or a value in marketplace. He explained about the limitation what "laws" can do to bound people's behavior and stressed importance of ethics to guide people's actions based on a set of values agreed in a civilized society.

Conclusion

We concluded that collaborative work of multidisciplinary teams are prerequisite especially in today's development and life cycle management of products utilizing advanced technology. We also clarified that continuing education and certification of all members of research teams as well as accreditation of clinical research sites and EC/IRBs along with establishment of ethical principles could provide more improved platform for global development.

References

1) Kerpel-Fronius S, Becker S, Barrett J, Brun J, Carlesi R, Chan A, Collia LF, Dubois DJ, Kleist P, Koski G, Kurihara C, Laranjeira LF, Schenk J, Silva H. The shared ethical responsibility of medically and non-medicallly qualified experts in human drug development teams. *Front Pharmacol*. 2018 Sep 3; 9: 843. doi: 10.3389/fphar.2018.00843. eCollection 2018.