Overview of Safety Management in Regenerative Medicinal Research

Hyeon Woo Yim[1]

[1]*Department of Preventive Medicine , College of Medicine, The Catholic University of Korea, Korea*

Y1693@catholic.ac.kr

Safety and efficacy of advanced therapy medicinal product must be confirmed through clinical trials in order to be developed and marketed it. Advanced therapy medicinal products can be caused unexpected safety problems because of the uncertainty of their inhomogeneity and differentiation potential characteristics.
The three-fold principle works when you want to confirm safety issues with a 95% probability in a clinical trial. For example, if you want to identify safety issues that occur in one among 1,000 people with a 95% probability, you need to analyze 3,000 who took the drug.
The Act on the “Safety and Support of Advanced Regenerative Medical and Advanced Biopharmaceuticals is a research law on advanced regenerative medicine and advanced biopharmaceuticals, which seeks to manage safety issues on Korean government initiative.
It will be presented on how to identify, evaluate, and manage safety issues that occur in clinical researches on advanced therapy medicinal products and how to identify, evaluate, and manage short-term and long-term safety issues, including, both expected and unexpected safety issues in this session.

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