Consideration for long-term follow-up studies of advanced biopharmaceuticals

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Advanced biopharmaceuticals including stem cell therapy, gene therapy and xenogenic cell/tissue based products may have the risk to remain in the human body for a considerable period of time after administration, resulting in delayed adverse events. Due to this risk, advanced biopharmaceuticals, unlike chemical drugs, require a new safety management system. In 2020, the “Advanced Regenerative Medicine and Advanced biopharmaceuticals Safety and Support Act” was enacted in Korea. The Korea Institute of Drug Safety and Risk Management(KIDS) was designated as a Center for Advanced biopharmaceuticals Regulatory Science which provides safety management and related support including research for regulatory affairs regarding advanced biopharmaceuticals. One of the main role of the center is supporting the long-term follow-up monitoring. Here I introduce the long-term follow-up investigation as a new regulations. I explain the obligations to be performed at each level of the clinical field including the Center for Regulatory Science, the Ministry of Food and Drug Safety, biopharmaceutical companies, and medical institutions. Finally, I will briefly introduce the other roles of the center, such as providing professional education and information about advanced biopharmaceuticals.

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