Asian Transplantation Week 2023

Nov. 15(Wed)~18(Sat), 2023
Conrad Seoul, Korea

Submission No.: XS02-9360
Session : Xenotransplantation Symposium 2
Date & Time, Place : November 18 (Sat), 11:00-12:30, Room 6F-1
Session Title : Road to the clinical trial: not an easy thing, may be

Strategy for the initiation of clinical trial of xenotransplantation

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Xenotransplantation, the process of transplanting organs or tissues from one species to another, has the potential to address the shortage of human donor organs for transplantation. This is a complex and highly regulated field with both great promise and significant challenges. It holds the potential to provide a new source of life-saving organs while raising important ethical, safety, and regulatory issues that must be carefully addressed in its development and implementation. Clinical trials of xenotransplantation are essential to assess its safety and efficacy. Especially, safety and ethical considerations should always be at the forefront of the research, and close collaboration with regulatory agencies is essential to bring potential xenotransplantation therapies to patients in a responsible manner. To lead successful clinical trials, it is required a multidisciplinary approach involving clinical pharmacologists, transplant surgeons, immunologists, and various other experts. From the clinical pharmacology perspectives, there are several important considerations when developing a strategy for clinical trials of xenotransplantation. These trials involve not only the surgical procedure but also the management of immunosuppression, safety, and efficacy assessments, and the monitoring of potential drug interactions. Furthermore, it is crucial to work closely with regulatory authorities, maintain transparency, and prioritize the ethical and safety considerations throughout the trial. The guidelines provided by the regulatory agencies and, experiences from new drug development and its clinical trials can offer valuable insights into establishing strategies to initiate clinical trials of xenotransplantation.