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## Remaining hurdles and future perspective

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In the field of xenotransplantation, recently, significant advances have been made and reported not only in non-human primate (NHP) preclinical model, but in trials in human. Two studies in kidney xenotransplantation decedent model using gene-editing (GE) pig have been performed and a patient received heart xenotransplantation survived several weeks. Many researchers believe that xenotransplantation will be advancing towards clinical challenge in very near future as a solution overcoming tremendous organ shortage. The introduction of CRISPR techniques makes it possible to produce multiple GE pigs within shorter research duration than ever. The xenotransplantation outcomes with various immune suppression regimens in non-human primate trials showed prolonged graft survival especially in heart and kidney transplantation. However, potential hurdles to clinical applications in various aspects have remained still unsolved or less prepared. More research is needed to determine what is the optimal GE pig according to individual organ supporting life. Some potent immune suppression agents showing outstanding xenotransplantation outcomes in preclinical NHP still have limitations and appear to be not sufficient to prepare them for clinical trials. The infection or transmission risk in xenograft recipients from porcine source animal remains one of the major concerns in clinical xenotransplantation. In the terms of regulatory controls, standards or guidelines to minimize the infection risk and ensure the safety in clinical trials, are essential and should include pre-transplant screening/monitoring of source animal in clinical grade facilities and monitoring in xeno-recipients after transplantation under the biorepository system. And the protocol or criteria that will minimize the risk and maximize the benefit of xenotransplantation in selected patients should be defined and prepared. In addition, from an ethical and religious standpoint, we need to inform the public about what is going on and discuss it with them. This presentation will look at recent advances in the field of xenotransplantation and summarize what is the hurdles and what we should prepare for successful clinical trials of xenotransplantation in patients overcoming organ shortage.