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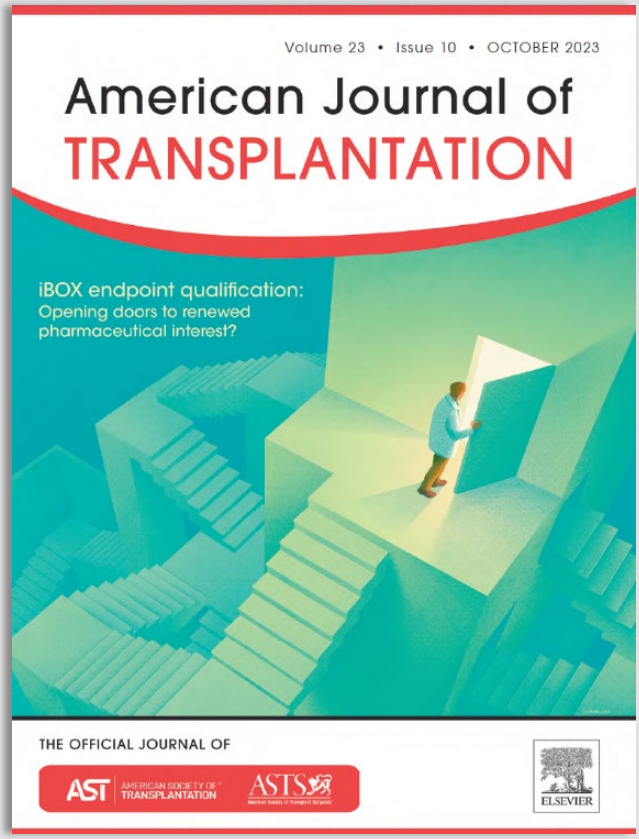

The October issue of AJT is now online.

Regulatory qualification of iBOX as an endpoint: will it boost drug development in transplantation?

The transplant community has long lamented the barren landscape of new immunosuppressants, feeling largely abandoned by pharmaceuticals due to the extreme difficulty and cost of executing registration trials. In December 2022, the European Medicines Agency (EMA) qualified the iBOX Scoring System, a short-term predictor of long-term death-censored kidney graft failure, as a novel secondary efficacy endpoint. Notably, for the EMA, this is the 1st approved endpoint in transplantation and only the 5th approved in all of medicine. Klein et al. delineate and Budde and Kaplan comment on the arduous process of regulatory qualification that required global collaboration and commitment by diverse stakeholders. *Cover design by Megan Llewellyn, CMI, Department of Surgery, Duke University.*

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