

Qualifying a novel clinical trial endpoint (iBOX) predictive of long-term kidney transplant outcomes

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Abstract

New immunosuppressive therapies that improve long-term graft survival are needed in kidney transplant. Critical Path Institute's Transplant Therapeutics Consortium received a qualification opinion for the iBOX Scoring System as a novel secondary efficacy endpoint for kidney transplant clinical trials through European Medicines Agency's qualification of novel methodologies for drug development. This is the first qualified endpoint for any transplant indication and is now available for use in kidney transplant clinical trials. Although the current efficacy failure endpoint has typically shown the noninferiority of therapeutic regimens, the iBOX Scoring System can be used to demonstrate the superiority of a new immunosuppressive therapy compared to the standard of care from 6 months to 24 months posttransplant in pivotal or exploratory drug therapeutic studies. You can read the manuscript in its original format, as published by the *American Journal of Transplantation*, here: [https://www.amjtransplant.org/article/S1600-6135\(23\)00416-1/abstract](https://www.amjtransplant.org/article/S1600-6135(23)00416-1/abstract)