

C-Path's Transplant Therapeutics Consortium's Work Highlighted in Recent Publication in the American Journal of Transplantation

C-Path's Transplant Therapeutics Consortium is pleased to announce the recent publication in?the *American Journal of Transplantation* by Klemens Budde and Bruce Kaplan, "<u>Stronger together: lessons from the iBox qualification process.</u>"

The article highlights TTC's work as the only community-based public-private partnership focused on reinvigorating drug development in transplantation.

As the manuscript states, "The close collaboration with the regulatory agencies and the creation of an open discourse forum with a pre-competitive and neutral, large data space aims to identify shared unmet needs of the transplant medical product development community. After five years of hard work the initial approval of the iBox for clinical registration trials marks the first successful output of this global initiative."

The iBOX received regulatory endorsement by EMA as a secondary efficacy endpoint for kidney transplant clinical trials with EMA. This is the first qualified endpoint for any transplant indication and is now available for use in kidney transplant clinical trials. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-ibox-scoring-system-secondary-efficacy-endpoint-clinical-trials-investigating_en.pdf