View Now: Workshop: Accelerating Medical Product Development in Kidney Transplantation Through a Public-private Partnership

C-Path's Transplant Therapeutics Consortium (TTC), in collaboration with key opinion leaders from academic institutions, the pharmaceutical and diagnostic industries, FDA, and the patient community, is excited to host an upcoming public workshop, "*Accelerating medical product development in kidney transplantation through a public-private partnership*" to be held virtually, **September 22, 8 a.m. to 12 p.m. ET**.

The workshop will cover the qualification process of a composite surrogate for long-term graft loss after kidney transplantation, use of real-world evidence (RWE) in transplant clinical trials, and future endpoints in kidney transplantation.

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This public workshop will focus on 1) qualifying a composite surrogate for long-term graft loss after kidney transplantation 2) real-world evidence use in transplant clinical trials and 3) potential future endpoints in kidney transplantation

TTC aims to accelerate the medical product development process for transplantation by identifying challenges, prioritizing solutions, and developing tools to advance new product development to meet the most pressing needs of transplant recipients.

Agenda:

Welcome
Session 1: Qualifying a composite surrogate for long-term graft loss after kidney transplantation • Regulatory qualification procedures and qualification status of the iBox Scoring System as a reasonably likely surrogate endpoint with FDA • Graphical user interface for sample size calculation using iBox scores • Panel discussion

Session 2: RWE use in transplant clinical trials

- Regulatory and design considerations for RWE supplementation in transplant clinical trials
- Pilot study for external control using the cyclosporine arm of the BENEFIT RCT versus UNOS/OPTN registry data
- Sample size calculation and use RWE for supplemental external controls for the 5-year survival analyses
- Panel discussion

Session 3: Future endpoints in kidney transplantation

- Efficacy endpoints
- Safety endpoints
- Regulatory qualification procedures for clinical outcome assessments
- Patient-reported outcome measures for transplantation
- Panel discussion

Closing Remarks

FDA acknowledgement