**Endpoints and Trial Designs to Advance Drug Development in Kidney Transplantation**

**AGENDA**
**November 9, 2023**
**FDA White Oak Campus**

**7:30 - 8:00 a.m. Registration**

**8:00 – 8:45 a.m. Opening**

- Welcome *(FDA) (J Corrigan-Curray and O Belen*) – 10 mins
- Are long-term outcomes after kidney transplantation improving? *(E Poggio)* – 20 mins
- Patient perspective *(P Conway, AAKP)* – 15 mins

**8:45 – 10:45 a.m. Session 1: Efficacy Endpoints for Kidney Transplant Prophylaxis of Rejection Trials** *(A Thompson/P Nickerson)*

- Current State of Primary Endpoints in Kidney Transplantation Trials *(E Velidedeoglu)* – 15 mins
- Surrogate Endpoints and Biomarkers – evidentiary criteria standards for Candidate/RLSE/Validated *(J Siegel)* – 15 mins
- iBOX as an endpoint EMA perspective – *(H Guðmundsdóttir)* – 15 mins
- iBOX as an endpoint C-Path/TTC perspective *(A Klein)* – 15 mins
- eGFR as an endpoint FDA perspective *(N Chaudhri)* – 10 mins
- eGFR as an endpoint Academia perspective *(R Mannon)* – 10 mins

Panel Discussion/Audience Q&A – *E Velidedeoglu/J Siegel/A Klein/N Chaudhri/R Mannon/N Nikolov* + Co-Moderators *(A Thompson, P Nickerson)* – 40 mins

**10:45 – 11:00 a.m. Break**

**11:00 a.m. – 12:15 p.m. Session 2: Biopsy Proven Acute Rejection (BPAR) Efficacy Failure** *(O Belen/R Mannon)*
**Current Regulatory Definition:** Composite of all BPAR events, as well as graft failure, death, or lost to follow-up in those subjects without BPAR.

- Defining BPAR – past, present, future? *(M Mengel)* – 15 mins
- Managing BPAR on contemporary immunosuppression: the transplant clinician perspective *(R Bloom)* – 15 mins
- Long-term impact of BPAR in the modern era – what do we know? *(P Nickerson)* – 15 mins

Panel Discussion/Audience Q&A – *R Bloom/M Mengel/P Nickerson* + Co-Moderators *(O Belen, R Mannon)* – 40 mins

**12:15 – 1:00 p.m. Lunch**

**1:00 – 2:30 p.m. Session 3: Non-Inferiority Trials – What have we learned?** *(N Chaudhri/R Bloom)*

- Identifying a non-inferiority margin for clinically acceptable loss of efficacy. *(K Higgins)* – 15 mins
- Importance of secondary efficacy endpoints including DSA. *(S Woodle)* – 15 mins
- Importance of safety endpoints: Focus on evidence-based pre-specification of key safety endpoints, hierarchical testing, and complete data collection. *(W Fitzsimmons)* – 15 mins

Panel Discussion/Audience Q&A – *K Higgins/S Woodle/W Fitzsimmons* + Co-Moderators *(N Chaudhri, R Bloom)* – 45 mins

**2:30 – 2:45 p.m. Break**

**2:45 – 3:45 p.m. Session 4: Personalized Immunosuppression / Enrichment as a tool in trial *design*** *(E Velidedeoglu/W Fitzsimmons)*

- What enrichment tools exist in kidney transplantation trials? *(C Wiebe)* – 15 mins
- Targeting subpopulations – It's time for personalized immunosuppressive therapy. *(P Heeger)* – 15 mins

Panel Discussion/Audience Q&A – *P Heeger/C Wiebe* + *K Fowler* Co-Moderators *(E Velidedeoglu/W Fitzsimmons)* – 30 mins

**3:45 – 4:25 p.m. Session 5: Workshop Takeaways & Wrap Up**

- Panel Discussion – Workshop Takeaways – Co-Chairs + AAKP + C-Path/TTC – *R Mannon/K Newell/M McCarthy* (AST Patient Representative) – 40 mins
- Closing comments – FDA *(O Belen)* – 5 mins