

6th KDCT Workshop • Virtual Edition: October 29 & 30, 2021 PRELIMINARY SCIENTIFIC PROGRAM

DAY 1: FRIDAY, OCTOBER 29, 2021



8:00 AM EST



14:00 CET

Introduction by KDCT Course Director Professor Patrick Rossignol (Nancy, FRA)

8:05 AM EST



14:05 CET

Session 1: KDCT in the eyes: latest renal results and key methodological and conduct insights from the FIDELIO/FIGARO/FIDELITY trials

Speaker George Bakris (Chicago, USA) Speaker Luis Ruilope (Madrid, ESP)



9:00 AM EST





Session 2: Hot Topic: which should be the most suitable comparator(s) in the next generation CKD trials?

Downstream the latest trials in proteinuric DKD (SGLT 2is, Finerenone) or in CKD without DM (dapagliflozin), the standard of care of CKD may encompass major changes. Should further trials consider head-to head comparisons with disease modifying drugs or an add-on approach? What about non proteinuric CKD (including DKD) trials too?

Moderator: Rajiv Agarwal (Minneapolis, USA)

Speaker George Bakris (Chicago, USA) Speaker Hiddo Heerspink (Groningen NED) Speaker Vlado Perkovic (Sydney, AUS) Speaker Christoph Wanner (Würzburg, GER) Discussant Meg Jardine (Sydney, AUS) Discussant Rajiv Agarwal (Indianapolis USA) Discussant Matthew Weir (Baltimore, USA) Discussant Sybille Hauske (Boehringer-Ingelheim, GER) Discussant Jerome Rossert (AstraZeneca, USA) Discussant Richard Nkulikiyinka (Bayer, GER) Discussant Ivonne Schulman (NIDDK, USA): NIDDK perspective Discussant Patrick Gee (Chesterfield, USA): patient's perspective **Discussants FDA, EMA, payers** Panel discussion

11:30 AM EST

Break

CONFIDENTIAL - NOT FOR SHARING

17:30 CET

DAY 1: FRIDAY, OCTOBER 29, 2021 (CONTINUED)

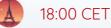
6th KDCT Workshop Virtual Edition: October 29 & 30, 2021

Session 3: AKI Trials

Moderator: Matthieu Legrand (San Francisco, USA)



12:00 PM EST



Part A: Pragmatic trials in AKI

When to use and how to succeed? The objective of this session is to discuss when and how to implement pragmatic trials in AKI, draw lessons from previous trials that may inform the design and the conduct of future trials and identify key-items for a roadmap toward AKI pragmatic trials implementation.

Speaker Jonathan Casey (Nashville, USA): Challenges and limits of clustered designs Speaker Kathleen Liu (San Francisco, USA): Use of Platform (including in the COVID-19 setting) trials Speaker Jay Koyner (Chicago, USA): eHR embedded trials Discussant F Perry Wilson (New Haven, USA): Insights from the Yale New Haven trial Discussant Sean Bagshaw (Alberta, CAN) Discussant Martin Gallagher (Sydney, AUS) Discussant Paul Palevsky (Pittsburgh, USA) Discussant Michael Mathis (Ann Arbor, USA) Discussant Amit Sharma (Bayer, USA) Discussant Ivonne Schulman (NIDDK, USA): NIDDK perspective Discussants FDA, EMA's perspective Panel discussion







Part B: How to better analyze and interpret AKI trials?

Should we move away from the frequentist approach and use alternative methods to interpret and analyze trials in AKI? Many trials have been negative raising the risk of missing important signals of benefit (or harm) in the studied population. How could we better identify potential subpopulation of interest, likelihood of success of failure of the tested strategies and heterogeneity of treatment effects in AKI trials.

Speaker Stephane Gaudry (Paris, FRA): What would I have done differently with my trial? Speaker Fernando Zampieri (São Paulo; BRA): Bayesian approach Speaker Romain Pirracchio (San Francisco, USA): Heterogeneity of treatment effects Discussant Steven Coca (New York City, USA) Discussant Ravindra Mehta (San Diego, USA) Discussant Alparslan Turan (Cleveland, USA) Discussant Sean Bagshaw (Alberta, CAN) Discussant Alexander Zarbock (Münster, GER) **Discussant** Juliane Bernholz (AM-Pharma, NED) Discussant Amit Sharma (Bayer, USA) Discussant NIDDK perspective: Ivonne Schulman (NIDDK, USA) **Discussants** FDA, EMA's perspective Panel discussion

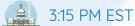
3:00 PM EST 21:00 CET

Break

DAY 1: FRIDAY, OCTOBER 29, 2021 (CONTINUED)



6th KDCT Workshop Virtual Edition: October 29 & 30, 2021





21:15 CET

Session 4: Special focus on IgA nephropathy: key insights from trials Moderator: Vlado Perkovic (Sydney, AUS)

Speaker Jürgen Floege (Aachen, GER): STOP-IgAN Speaker Hiddo Heerspink (Groningen, NED): DAPA-CKD Discussant David Sjöström (AstraZeneca, USA) Speaker Jonathan Barratt (Leicester, GBR): NEFIGARD Discussant Calliditas Speaker Muh Geot Wong (Sydney, AUS): PROTECT Discussant Travere Speaker Vlado Perkovic (Sydney, AUS): APPLAUSE Discussant Marty Lefkowitz (Novartis, USA) Discussant Chinook Therapeutics, USA: Portfolio/basket trials in igAN Discussant FDA, USA: FDA insights: accelerated vs full approval insights Discussants EMA, payers, patient's perspective Panel discussion

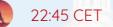
Session 5: Vascular Access Devices

Moderator: Prabir Roy-Chaudhury (Chapel Hill, USA)

Dialysis vascular access is the lifeline for patients on hemodialysis but due to the many complications associated with all forms of dialysis vascular access it is also the Achilles heel of hemodialysis. This session will highlight both the challenges and opportunities ahead of us as we attempt to create a true innovation substrate for dialysis vascular access.



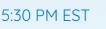
4:45 PM EST



PART A: The Dialysis Access Collaborative Community

Speaker Prabir Roy-Chaudhury (Chapel Hill, USA): Coordinated registry networks and pragmatic trials for vascular Access: the Dialysis Access Collaborative Community (DACC) initiative Speaker Nichole Jefferson (Dallas, USA): The patient perspective on vascular access: of disparity, despair and hope Speaker Caroline Wilkie (Punta Gorda, USA): The patient perspective on vascular access: of disparity, despair and hope Discussant Melissa West (KHI USA)





23:30 CET

PART B: From Concept through clinical trials and to the clinic

Speaker Peter Schneider (San Francisco, USA): From the concept to a study device Speaker Carmen Gacchina Johnson (FDA, USA): FDA regulatory pathways for device approval Speaker Rohini Retarekar (FDA, USA): Engineering considerations in device development Speaker Robert Lee (FDA, USA): Challenges in clinical trials of access devices Speaker Karen Woo (FDA, USA): The role of patient reported outcomes Speaker Dheeraj Rajan (Toronto, CAN): Regulatory approval is not enough: we need real world data! Speaker Charmaine Lok (Toronto, CAN): How new technology Impacts clinical practice guidelines Discussant Anna Szafranski (Medtronic, USA) Discussant Josh Smale (Becton Dickinson, USA) Panel discussion

7:30 PM EST 1:30 CET (Saturday)

Adjourn

DAY 2: SATURDAY, OCTOBER 30, 2021



6th KDCT Workshop Virtual Edition: October 29 & 30, 2021



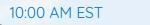


14:30 CET

Session 6: Contactless/decentralized/virtual trials/ registry trials in CKD: challenges and opportunities Moderator: Meg Jardine (Sydney, AUS)

Speaker Pierre-Henri Bertoye (Paris, France): IRB-EU perspective Speaker Ann Maxe (AstraZeneca, USA): Industry perspective on virtual trials Speaker Meg Jardine (Sydney, AUS): Global cluster randomized trials Discussant Hiddo Heerspink (Groningen, NED) Discussant Laura Dember (Philadelphia, USA) Discussant William Herrington (Oxford, GBR) Discussant Ivonne Schulman (NIDDK, USA): NIDDK perspective Discussant Cynthia Chauhan (Wichita, USA): patient's perspective Discussants FDA, EMA, payers Panel discussion



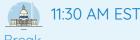


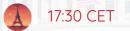
16:00 CET

Session 7: Central lab vs local lab vs at home point of care?

Example: albuminuria as a surrogate but this may apply to other biological parameters assessed for screening/safety purposes (potassium, eGFR, Hb, albuminuria at home, new technologies) Moderator: Christoph Wanner (Würzburg, GER)

Speaker Winfried März (Mannheim, GER): Slopes and lab surrogates require precise measurements Speaker Richard Haynes (Oxford, GBR): Large pragmatic trials - randomization is key, precision is secondary Speaker Katherine Landschulz (Labcorp Drug Development, USA): New technologies on the horizon Discussant Harold Feldman (Philadelphia, USA) Discussant Mathias Kretzler (Ann Arbor, USA) Discussant Alain Romero (Chinook Therapeutics, USA) Discussant Erwin Berthier (Tasso Inc, USA): At home blood collection Discussant Maurice Berenger (CardioRenal, FRA): Blood potassium monitoring at home Discussant Healthy iO, USA: Home urinalysis Discussant Ivonne Schulman (NIDDK, USA): NIDDK perspective Discussant Cynthia Chauhan (Wichita, USA): patient's perspective Discussants FDA, EMA, payers











Session 8: Focus on stage 4 CKD trials: key insights from trials (primarily) targeting blood pressure Moderator: Patrick Rossignol (Nancy, FRA)

Speaker George Bakris (Chicago, USA) Speaker Rajiv Agarwal (Minneapolis, USA) Discussant Matthew Weir (Baltimore, USA) Discussant Fred Yang (KBP Biosciences, USA) Discussant Bruno Flamion (Idorsia, USA) Discussant Ivonne Schulman (NIDDK, USA): NIDDK perspective Discussants FDA, EMA, payers, patient's perspective Panel discussion

DAY 2: SATURDAY, OCTOBER 30, 2021 (CONTINUED)



6th KDCT Workshop Virtual Edition: October 29 & 30, 2021





19:30 CET

Session 9: Key insights from trials targeting fluid overload and its assessment in chronic hemodialysis Moderator: Prabir Roy-Chaudhury (Indianapolis, USA)

Speaker Jennifer Flythe (Chapell Hill, USA) Speaker Carmine Zoccali (Reggio di Calabria, ITA): Ultrasound lung water: the LUST Study Speaker Adrian Covic (lasi, ROM): Bioimpedance low phase angle indicators Discussant John Daugirdas (Chicago, USA) Discussant Rajiv Agarwal (Indianapolis, USA) Discussant Jule Pinter (Würzburg, GER) Discussant Ulrich Moissl (Fresenius, Bad Homburg, GER) Discussant Peter Blankestijn (Utrecht, NED): Convection with conviction to CONVINCE Discussant Steven Brunelli (Davita, USA) Discussant Colleen Brophy (Volumetrix, USA) Discussant Ivonne Schulman (NIDDK, USA): NIDDK perspective Discussants FDA, EMA, payers, patient's perspective

Panel discussion





Break







Session 10: Diversity in nephrology trials: Promoting diversity in kidney disease trials Moderator: Luis Ruilope (Madrid, ESP)

Speaker Kirk Campbell (New York City, USA) Speaker Neil Powe (San Francisco, USA) Discussant Barbara Gillespie (Labcorp Drug Development, USA) Discussant Emma Schroeter (H1, USA) Discussant TBD: Editor's perspective Speaker Lesley Inker (Boston, USA): Estimation of glomerular filtration rate with vs without including patient ethnicity: impact on clinical trials conduct? Discussant Harold Feldman (Philadelphia, USA) Discussant David Charytan (New York City, USA) Speaker Bessie Young (Seattle, USA): Genetic contributions to disease progression (APOL-1 risk variants) Discussant Ivonne Schulman (NIDDK, USA): NIDDK perspective Discussant Patrick Gee (Chesterfield, USA): patient's perspective Discussants FDA, EMA, payers Panel discussion

Final words by KDCT Course Director Professor Patrick Rossignol (Nancy, FRA)

22:45 CET



4:45 PM EST

23:00 CET

