KIDNEY DISEASE CLINICAL TRIALISTS

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 15:00 CET

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 17:30 CET

Break

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

Session 3: AKI Trials

Moderator: Matthieu Legrand (San Francisco, USA)

12:00 PM EST — 18:00 CET

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

1:30 PM EST — 19:30 CET

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)

3:15 PM EST 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
Discussant Ivonne Schulman (NIDDK, USA): NIDDK perspective
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 22:45 CET

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)

5:30 PM EST 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 Mark Ohan (WL Gore, USA)
Discussant Josh Smale (Becton Dickinson, USA)
Panel discussion

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

Adjourn

DAY 2: SATURDAY, OCTOBER 30, 2021

8:30 AM EST 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

10:00 AM EST 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

11:30 AM EST 17:30 CET

Break

12:00 PM EST 18:00 CET

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)

1:30 PM EST 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 (Iasi, 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

3:00 PM EST 21:00 CET

Break

3:15 PM EST 21:15 CET

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

4:45 PM EST 22:45 CET

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

5:00 PM EST 23:00 CET

Adjourn