MARCH 3-4, 2023 • EMBASSY OF FRANCE, WASHINGTON DC

SCIENTIFIC PROGRAM

DAY 1: FRIDAY, MARCH 3, 2023

8:30 AM EST 14:30 CET

Introduction by KDCT Course Director Professor Patrick Rossignol (Monaco, MON)

8:35 AM EST 14:35 CET

Session 1A: ACUTE KIDNEY INJURY - ENRICHMENT STRATEGIES IN SEPSIS

Moderator: M Legrand (San Francisco, USA) & L Dember (Philadelphia, USA)

- Why Sepsis-associated AKI should be considered as a specific entity?

Speaker: M Osterman (London, GBR)
Discussant: I Schulman (NIDDK, USA)

- Which endpoints matter to patients and their relatives?

Speaker: R Mehta (San Diego, USA)
Discussant: S Bagshaw (Edmondton, CAN)

- Subphenotyping of AKI

Speaker: A Bihorac (Gainesville, USA)
Discussant: R Mehta (San Diego, USA)

- Biomaker-guided enrichment strategy in Sepsis

Speaker: J Koyner (Chicago, USA)
Discussant: P Bhatraju (Seattle, USA)

Discussant: Payer's perspective A Ryan (CMS, USA)

- Panel discussion

All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

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09:55 AM EST 15:55 CET

SESSION 1B: ACUTE KIDNEY INJURY - PREVENTING AKI IN PATIENTS WITH SEPSIS OR DISTRIBUTIVE SHOCK

Moderator: M Legrand (San Francisco, USA) & R Mehta (San Diego, USA)

- RCTs that changed clinical practice : the example of vasopressors

Speaker: A Khanna (Winston-Salem, USA)
Discussant: A Zarbock (Münster, GER)

- Pragmatic trials to prevent AKI in the critically ill

Speaker: M Legrand (San Francisco, USA)
Discussant: L Dember (Philadelphia, USA)

- The risk of underpowered trials in sepsis

Speaker: F Zampieri (Edmondton, CAN)
Discussant: M Harhay (Philadelphia (USA)

- Emulated target trial

Speaker: E Caniglia (Philadelphia, USA)
Discussant: M Gallagher (Sydney, AUS)

- Panel discussion

All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

Coffee break

INDICATES REMOTE PARTICIPANT

DAY 1: FRIDAY, MARCH 3, 2023 (CONTINUED)

11:30 AM EST 17:30 CET

SESSION 1C: ACUTE KIDNEY INJURY : DESIGN CONSIDERATION FOR PH2 STUDIES

Moderator: M Legrand (San Francisco, USA) & M Gallagher (Sydney, AUS)

- Which endpoint for phase 2 trials?

Speaker: P Pickkers (Nijmegen, NED)
Discussant: K Chung (SeaStar Medical, USA)

- From phase 2 to phase 3 trials

Speaker: J Kellum (Pittsburgh, USA)
Discussant: J Bernholz (AM-Pharma, NED)

- Role of platform trials

Speakers: K Liu (San Francisco, USA)
Discussant: P Pickkers (Nijmegen, NED)

- Panel discussion

All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

Lunch break

1:50 PM EST 19:30 CET

SESSION 2: KDCT IN THE EYES: DOWNSTREAM EMPA-KIDNEY

Moderator: B Neuen (Sydney, AUS) & P Rossignol (Monaco, MON)

- Keynote Lecture: C Wanner (Würzburg, GER)
- Speaker: The evolution of pillars of therapy G Bakris (Chicago, USA)
- Speaker: Extending the use of SGLT2 inhibitors beyond the present label (The LifeCycle Trial) R Gansevoort (Groningen, NED)
- Discussant: M Jardine (Sydney, AUS)
- Discussant: Industry Perspective D Steubl (Boehringer Ingelheim, GER)
- Discussant: Industry Perspective J Rossert (Astra Zeneca, USA)
- Discussant: Patient Perspective P Gee (iAdvocate, Inc., USA)
- Panel discussion

All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

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3:10 PM EST 21:10 CET

SESSION 3: RESISTANT/UNCONTROLLED HYPERTENSION IN CKD DRUGS AND DEVICES: EXPLORING THE FUTURE

Moderator: P Rossignol (Monaco, MON)

- Should all completed, ongoing, scheduled, phase 3 trials (active vs placebo) be positive? How to best implement the results?

Speaker: G Bakris (Chicago, USA)
Discussant: L Ruilope (Madrid, ESP)

- Trials insights

Discussant: Insights from the CLICK trial R Agarwal (Indianapolis, USA)
Discussant: Insights from the Precision trial B Flamion (Idorsia Pharmaceuticals, SUI)
Discussant: Insights from the BrigHtn trial W Marshall (Cincor Pharma, USA)
Discussant: Insights from the BLOCK CKD trial F Yang (KBP Biosciences, USA)
Discussant: Renal denervation trials D Hettrick (Medtronic, USA)
Discussant: Radiance II renal denervation trial D Augustin (ReCor Medical, USA)

- Panel discussion

All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

Coffee break

4:45 PM EST 22:45 CET

SESSION 4: WIN RATIOS AS ENDPOINTS IN NEPHROLOGY TRIALS

Moderator: M Jardine (Sydney, AUS)

Speaker: Investigator perspective H Heerspink (Groningen, NED)
Discussant: Kidney insights from the DIAMOND trial M Weir (Baltimore, USA)
Discussant: Statistician perspective C Tasto (Bayer, GER)
Discussant: Statistician perspective S Gasparyan (AstraZeneca, SWE)
Discussant: Industry perspective J Rossert (AstraZeneca, USA)
Discussant: Industry perspective R Nkulikiyinka (Bayer, GER)

- Panel discussion

All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

Coffee break

6:15 PM EST 00:15 CET

SESSION 5: PROS IN HEMODIALYSIS TRIALS

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

Core outcomes dataset in hemodialysis, as defined by the SONG initiative, encompass PROs (e.g fatigue). Using PROs as endpoints in pivotal studies and the acceptance by regulators are a new concept. Using PROs in dialysis care requires some change in nephrology routine, acknowledging the usual discordance between symptoms reported by patients and those identified by their nephrology care-providers

Speaker: G Chertow (San Francisco, USA)
Discussant: SONG-HD Fatigue measurement initiative A Jauré (Sydney, AUS)
Discussant: Impact of CKD-associated pruritus on QOL in dialysis D Rüssmann (CSL Vifor, SUI)
Discussant: How to best manage the placebo effect M Murphy (Worldwide Clinical Trials, USA)
Discussant: Patient perspective C Chauhan (Wichita, USA)

- Panel discussion

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DINNER IN THE EMBASSY

DAY 2: SATURDAY, MARCH 4, 2023

8:30AM EST 14:30 CET

SESSION 6: TARGETING KIDNEY ENDPOINTS IN TRIALS IN PATIENTS WITH SICKLE CELL DISEASE (SCD)

Moderator: Meg Jardine (Sydney, AUS)

SCD is the most common inherited blood disorder. Most of the trials have used primary end-points of painful vaso-occlusive crisis (VOCs), including gene therapy trials but emphasis is now on organ damage prevention of which kidney, lungs, brain seem to be the most discussed (no organ is spared). Key Questions for clinical trials to discuss:

- What is the natural history of SC nephropathy, specifically the course of albuminuria and GFR?
- Characterize risk relationships between changes in albuminuria, eGFR, and clinical endpoints (ESKD).
- What can we do to support the choice of meaningful endpoints and metrics for clinical trials (composite Hb, Alb?)
- What are appropriate volunteers for a renal study in SCD ? How to select trial populations based on GFR and albuminuria balancing risk and feasibility?
- What can we do to improve recruitment of affected populations?

Speaker: Investigator perspective S Saraf (Chicago, USA)
Discussant: Nephrologist's perspective V Derebail (Chapel Hill, USA)
Discussant: Industry perspective A Romero (Pfizer, USA)
Discussant: Industry perspective K Uhlig (Agios, USA)

- Panel discussion

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DAY 2: SATURDAY, MARCH 4, 2023 (CONTINUED)

09:40 AM EST 15:40 CET

SESSION 7: NEW INSIGHTS FROM eGFR SLOPES?

Moderator: L Ruilope (Madrid, ESP)

Speaker: H Heerspink (Groningen, NED)
Discussant: M Jardine (Sydney, AUS)
Speaker: Impact of frequent creatinine measurements on clinical studies assessing CKD progression R Myte (AstraZeneca, USA)
Speaker: Association of CKD progression and regression with ESKD and MACE B Tyl (Bayer, GER)
Discussant: Industry perspective E Welch (Tasso Inc., USA)
Discussant: Patient Perspective P Gee (iAdvocate, Inc., USA)

- Panel discussion

All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

Coffee break

11:20 AM EST 17:20 CET

SESSION 8: PROGNOSTIC ENRICHMENT FACTORS /STRATEGIES WHEN DESIGNING PH3 STUDIES IN CKD

Moderator: C Wanner (Würzburg, GER)

Speaker: G Chertow (San Francisco, USA)
Speaker: Screening for CKD to identify subjects at risk for CKD progression and CV events - Insights from the THOMAS study R Gansevoort (Groningen, NED)
Discussant: Enrichment and precision medicine strategies for vascular access and dialysis P Roy Chaudhury (Chapel Hill, USA)
Discussant: I Davidson (Dallas, USA)
Discussant: Industry perspective T Idorn (NovoNordisk, DEN)
Discussant: Industry perspective A Obergfell (CSL Vifor, SUI)

Panel discussion
All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

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12:40 PM EST 18:40 CET

SESSION 9: CONDITIONAL APPROVAL, EXPEDITED REVIEW AND RELATED METHODOLOGICAL ISSUES

Moderator: G Bakris (Chicago, USA)

There are several programs intended to facilitate and expedite the review and approval of new treatments for serious diseases with unmet needs. This session will focus on opportunities as well as challenges related to the use of these programs. For example, in rare kidney diseases, the same trial may be used to support initial approval (via FDA's accelerated approval pathway in the US and EMA's conditional approval pathway in Europe) and also verify the clinical benefit in the postmarketing setting. This has raised concerns about the release of interim data from the trial and whether the release of such information could impact the integrity of the data from the second phase/confirmatory phase of the trial.

Speaker: Investigator perspective J Barratt (Leicester, GBR)
Speaker: Statistician's perspective J Zhang (FDA, USA)
Speaker: CDER perspective R Kambhampati (FDA, USA)
Speaker: FDA's Breakthrough Devices Program: Expediting Review of Promising Technology R Lee (FDA, USA)
Speaker: CBER perspective V Kumar (CBER, USA)

Panel discussion
All speakers and discussants above joined by FDA, EMA, NIH, Industry, Payer and Patient representatives

Final words by KDCT Course Director Professor Patrick Rossignol (Monaco, MON)

2:00 PM EST 20:00 CET

Adjourn & lunch
(lunchboxes and drinks will be provided)