FDA-University of Maryland CERSI

ADEPT 8: Workshop on drug dosing in Pediatric Patients with Renal Impairment

Agenda

Day 1 – Thursday, November 30, 2023

9:00 – 9:05 a.m. Welcome - **Lily Mulugeta (FDA) and Bakri Alzarka (Univ. of Maryland)**

9:05 - 9:15 a.m. Introductory remarks - **FDA**

9:15 - 9:25 a.m. Setting the scene - **Shamir Tuchman (FDA)**

9:25 – 9:35 a.m. Opening presentation - **Martina Sahre (FDA)**

9:35 - 9:45 a.m. Drug clearance in pediatric patients with renal impairment - **Saskia de Wildt (Radboud Univ. Medical Center)**

9:45 – 9:55 a.m. Case example: Avycaz (Abbvie) - **Henrietta Abodakpi (FDA)**

Session 1: What constitutes as renal impairment in pediatric patients for the purposes of PK characterization and drug dosing?

Academic Perspective: Considerations around assessment of renal function

9:55 – 10:10 a.m. Strengths and limitations of existing estimation methods and applications to specific population - **George Schwartz (Univ. of Rochester Medical Center)**

Clinical Perspective: Considerations around assessment of renal function and drug dosing

10:10 – 10:30 a.m. What clinicians and other stakeholders need to know about special populations **Guido Filler (Western Univ. – London, Ontario, Canada; Children's Hospital, London Health Sciences Centre)**

Industry Perspective: Considerations around assessment of renal function in the context of clinical trial

10:30 – 10:45 a.m. **Speaker 1: Ashish Sharma (Boehringer-Ingelheim)**

10:45 – 11:10 a.m. **Speakers 2 and 3: Nicholas Webb and Deepa Chand (Novartis)**

11:10 – 11:30 a.m. **BREAK**

11:30 a.m. -1:00 p.m. Moderated Panel Discussion and Q&A

Moderators: Mona Khurana (FDA) and Bakri Alzarka (Univ. of Maryland)

Panelists:

- Shamir Tuchman (FDA)
- Martina Sahre (FDA)
- Deepa Chand (Novartis; Univ. of Illinois College of Medicine)

- Nicholas Webb (Novartis)
- Afshin Parsa (NIH)
- George Schwartz (Univ. of Rochester Medical Center)
- Guido Filler (Western Univ. – London, Ontario, Canada**)**

1:00 - 2:00 p.m. **LUNCH**

Session 2: Translating adult renal impairment data in pediatric patients with renal impairment

2:00 – 2:10 p.m. Recap of Case Example: Avycaz (Abbie) - **Henrietta Abodakpi (FDA)**

2:10 – 2:25 p.m. Translating adult renal impairment PK data—Academic/clinical perspective **Saskia de Wildt (Radboud Univ. Medical Center)**

2:25 -2:40 p.m. Reliance on BSA indexed GFR values versus individualized eGFR values to guide drug dosing in adults and implications to pediatrics - **Thomas Nolin (Univ. of Pittsburgh School of Pharmacy)**

2:40 – 4:30 p.m. **Moderated Panel Discussion and Q&A**
Moderators: Lily Mulugeta (FDA) and Tsuyoshi Fukuda (Eli Lilly)
Panelists:

- Lynne Yao (FDA)
- Martina Sahre (FDA)
- Vikram Sinha (Novartis)
- Rebecca Wrishko (Merck)
- Saskia de Wildt (Radboud Univ. Medical Center)
- George Schwartz (Univ. of Rochester Medical Center)
- Jeff Barrett (Aridhia)
- Thomas Nolin (Univ. of Pittsburgh School of Pharmacy)
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4:30 – 4:40 p.m. **Summary and closing -** Lily Mulugeta (FDA) and Bakri Alzarka (UMD)

Day 2 – Friday, December 1, 2023

Session 3: Future Directions: Dosing in pediatric patients with renal impairment

Role of modeling and simulation

9:00 - 9:10 a.m. Considerations for modeling and simulation for pediatric renal impairment - **Justin Earp (FDA)**

9:10 – 9:20 a.m. Role of systems biology modeling in extrapolating efficacy and safety from adult renal impairment data – **Karim Azer (Rutgers Univ.)**

9:20 – 10:30 a.m. **Moderated Panel Discussion and Q&A**
Moderators: Elimika Pfuma Fletcher (FDA) and Jeff Barrett (Aridhia)
Panelists:

- Jason Moore (FDA)
- Hao Zhu (FDA)
- Saskia de Wildt (Radboud Univ. Medical Center)
- Sonya Tang Girdwood (Cincinnati Children's)
- Liping Zhang (Johnson & Johnson)
- Karim Azer (Rutgers Univ.)
- Efthymios Manolis (EMA)
- Pieter Colin (EMA)

10:30 – 10:45 a.m. BREAK

Approaches for generating clinical trial data to assess impact of RI on PK in pediatric patients

10:45 – 10:55 a.m. Industry perspective; **Jan Marquard (Boehringer-Ingelheim)**

Labeling considerations

10:55 – 11:05 a.m. Su-Young Choi (FDA)

11:05 a.m. - 12:05 p.m. Moderated Panel Discussion and Q&A
Moderators: Lynne Yao (FDA) and Bakri Alzarka (Univ. of Maryland)
Panelists:

- Kirtida Mistry (FDA)
- Gil Burckart (FDA)
- Bradley Warady (Children's Mercy Kansas City)
- Adam Levy (BMS Pediatric Center of Excellence)
- Ashish Sharma (Boehringer-Ingelheim)
- Jan Marquard (Boehringer-Ingelheim)
- Susan Mendley (NIH)
- Guido Filler (Western Univ; Children's Hospital, London Health Sciences Centre)

12:05 – 12:15 p.m. Summary and Closing Remarks - Lynne Yao, FDA