

PARASOL (Proteinuria and GFR as Clinical Trial Endpoints in Focal Segmental Glomerulosclerosis)

Scientific Workshop

Bethesda, Maryland | October 7-8, 2024

Venue: Bethesda Marriott, 5151 Pooks Hill Rd

Agenda

NON-FINAL DRAFT – subject to programming changes

Monday, October 7

12 noon: Lunch

1 pm-3pm: Proteinuria and GFR as Clinical Trial Endpoints in FSGS

1 PM: Why PARASOL? Background and Unmet Need – Laura Mariani and Josh Tarnoff

1:15 PM: Patient Panel

1:45–2:00: Break

2:00: Regulatory Perspective: Endpoints in FSGS - Aliza Thompson

2:20: Data Sources and Statistical Analysis Methods – Margaret Helmuth

2:40: Break (with refreshments)

3 pm-6pm: Applications

3:00: Summary of findings from Reykjavik – Abigail Smith

eGFR Findings – Ulysses Diva

3:45 Biological Plausibility – Tobias Huber

4:00 Break

4:15 Results: Modeling Proteinuria

Overall – Abigail Smith

Proposed Endpoints

4:45 Validation from the UK RaDaR Registry – Moin Saleem, Danny Gale

5:00 Q&A on analysis - Margaret Helmuth, Abigail Smith, Alex Mercer, David Pitcher, Jialu Zhang, Dali Zhou, William Koh

5:30: Panel – Nephrology Community Feedback (Moderated by Barbara Gillespie)

Sayna Norouzi, Keisha Gibson, Brad Rovin, Gaia Coppock, Shikha

Wadhvani

7 pm: Dinner

Tuesday, October 8

(Time TBD): EMA commentary

Frank Holtkamp, Karin Janssen Van Doorn, Thorsten Vetter

8:00 am: Planning for the Future

8:00 – 9:00 Using PARASOL Findings to Inform Clinical Trial Planning: Options and Pathways – Alex Mercer, Ulysses Diva, Aliza Thompson, Rekha Kambhampati

9:00 Commentary: Aliza Thompson

9:15 Break

9:45 Publication plans, further analysis, ASN presentation

10:00 What's next? – Matthias Kretzler and Laurel Damashek

10:45 Break (with refreshments; hotel check-out)

11:15 Discussion

12:00 Lunch / close