

# Proteinuria and GFR as Clinical Trial Endpoints in Focal Segmental Glomerulosclerosis

### Interim Meeting June 8-9, 2024

#### Locations

- Meeting Venue: Hannesarholt (<u>Grundarstígur 10, 101 Reykjavík</u>)
- Fosshotel Reykjavík: Þórunnartún 1, 105 Reykjavík
- Exeter Hotel: Tryggvagata 12, 101 Reykjavík
- Aurora Basecamp (Saturday offsite dinner): 417, 221 Hafnarfjörður

#### Wi-Fi

Hljóðberg, main meeting room Network: hljodberg password: jonjon2017 1st and 2nd floor Network: Hannesarholt password: steinn2017

**Q&A form** to use during meeting: https://forms.gle/4WumV8iuX5NDAzjm7

#### **Zoom Information**

Please note the separate Zoom links/meeting ID and passcode for Saturday and Sunday.

#### **SATURDAY**

#### Zoom link

https://us06web.zoom.us/j/86375715896?pwd=TxNgigjAtw6ss3eip8TaRQvbd1Rl0g.1

Passcode 510657

Meeting ID 863 7571 5896

Local dial-in numbers: https://us06web.zoom.us/u/kcPlqFcWu

#### **SUNDAY**

#### Zoom link

https://us06web.zoom.us/i/88636465221?pwd=ntXFJ8g06RiJowXEzlBpedcbjzsKND.1

Passcode 610138

Meeting ID 886 3646 5221

Local dial-in numbers: https://us06web.zoom.us/u/kcPlqFcWu

#### **QUESTIONS? PLEASE CONTACT:**

#### Logistics:

- Glory Onwuka, ISGD Operations Project Manager gonwuka@is-gd.org
- Úlfhildur Bjarnason (Úlla), G-Events Meeting Planner <u>ulla@g-events.is</u>
   Mobile: +354 6990441

#### **Meeting Content:**

- Laura Mariani, PARASOL PI <a href="mariani@umich.edu">lmariani@umich.edu</a>
- Laurel Damashek, ISGD Executive Director <u>Idamashek@is-gd.org</u>
   Mobile: +1 617 286 2388

# **Agenda**

All times listed in Iceland time zone: GMT (UTC +0). Convert to your time zone here.

#### Friday June 7, 2024

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Time		Activity
	7:30 PM-9:30	Informal Dinner: Haust Restaurant at Fosshotel
	PM	Please drop in for dinner anytime between 7:30 and 9, if your travel plans
		allow.

Saturday June 8, 2024

Time	Activity
iol	Breakfast at hotels (Coffee & tea will be available at meeting venue)
₹ 7:40 AM	Bus Pickup at Fosshotel Dropoff 8:00 am at Lækjargata bus stop (5-7 min walk to Hannesarholt meeting venue)
8:15 AM	All participants arrive at Hannesarholt
8:30 AM	Meeting Opening/Welcome Josh Tarnoff; Hrefna Gudmundsdottir; Matthias Kretzler
9:00 AM	FDA Perspective of Endpoint Model Development  Aliza Thompson
9:30 AM	PARASOL Status Overview Tobias Huber
10:00 AM	Analytic Roadmap Laura Mariani, Abigail Smith, Margaret Helmuth
	BREAK Refreshments available
11:00 AM	eGFR Data and Discussion Presenters: Abigail Smith, Margaret Helmuth, Ulysses Diva Moderator: Danny Gale
12:15 PM	LUNCH Lunch provided at Hannesarholt
1:30 PM	UPCR and eGFR (Accelerated Approval Pathway) Data and Discussion Presenters: Alex Mercer, Margaret Helmuth Moderator: Alex Mercer
<b>₹</b> 2:15 PM	BREAK Refreshments available
2:30 PM	UPCR and Kidney Failure (Traditional Approval Pathway) Data and Discussion Presenter: Abigail Smith

Time	Activity
	Moderator: Keisha Gibson
3:15 PM	Patient Perspective Kevin Fowler
3:30 PM	Transition to breakout groups
3:45 PM	Stress Testing the Model: What is needed to convince you?  Group 1: Clinicians (Moderators: Kirk Campbell, Bill Smoyer)  Group 2: Statisticians (Moderator: Cathie Spino)  Group 3: Industry representatives (Moderator: Uptal Patel)  Group 4: Virtual (Stéphan Troyanov, Kerry Willis)
4:45 PM	Transition to large group
5:00 PM	Report Outs Moderator: Barbara Gillespie
5:45 PM	Adjourn Laurel Damashek
<b>≅</b> 6:00 PM	Bus to Fosshotel Bus will depart from Lækjargata bus stop promptly at 6:00
፟ <b>፷</b> 7:00 PM	Buses depart from Fosshotel and Exeter Hotel to Aurora Basecamp (Separate buses, 1 per hotel) Note: Our dinner location is not reachable by public transit; please be on time for the bus
7:30 PM	Offsite Dinner Aurora Basecamp, (417, 221 Hafnarfjörður, about 30 minutes from Reykjavik)
<b>≡</b> 10:00 PM	Return buses depart Aurora Basecamp for Fosshotel and Exeter Hotel (Separate buses, 1 per hotel)

## Sunday June 9, 2024

Time	Activity
	Breakfast at hotels (Coffee & tea will be available at meeting venue)
<b>≅</b> 7:20 Æ	M Bus Pickup at Fosshotel Dropoff 7:30 am at bus stop at Lækjargata bus stop (5-7 min walk to Hannesarholt meeting venue)
7:45 A	M All participants arrive at Hannesarholt
8:00 A	M Meeting Opening/Welcome Josh Tarnoff

8:05 AM	Goalpost for October & Proposed Analyses Panel: Aliza Thompson, Laura Mariani, Abigail Smith, Barbara Gillespie, Melissa West
8:45 AM	Transition to breakout groups
9:00 AM	<ul> <li>Breakout groups</li> <li>Group 1: Pediatrics (Moderator: Rasheed Gbadegesin)</li> <li>Group 2: Medications (Moderator: Vimal Derebail)</li> <li>Group 3: Subgroups (Moderator: Alessia Fornoni)</li> <li>Group 4: Trial design impact (Moderator: Hiddo Heerspink)</li> </ul>
9:45 AM	Transition to large group
10:00 AM	Report Outs Moderator: Barbara Gillespie
₹ 10:30 AM	Break Refreshments available
10:45 AM	Future of PARASOL Brad Rovin, Matthias Kretzler
11:45 AM	Wrap Up Tobias Huber
12:00 PM	Adjourn; Lunch Lunch provided at Hannesarholt
■ 12:45 PM	Bus returns to Fosshotel Bus will depart from Lækjargata bus stop promptly at 12:45

Thank you for joining us!

