Day 1: Friday, November 13 — Galveston Island Convention Center - GICC

Time	Session	Speakers	Location
Registration Opens at 8:30 AM on Level 1 at the Side Entrance closest to the Hilton			
8:30 AM - 10:00 AM	**Refreshments available**		GICC **Level 2: Grand Ballroom Foyer**
10:15 AM - 10:30 AM	Welcome by ISGD & UTMB Leadership	**Tobias B. Huber** **Jochen Reiser**	GICC **Level 2: Grand Ballroom**
10:30 AM - 10:40 AM	Texas Welcome	**The Honorable Randy Weber**	GICC **Level 2: Grand Ballroom**
10:40 AM - 11:10 AM	Keynote Address "Faster Science: How AI is Rewriting the Pace of Clinical Trials"	**Kedar Mate**	GICC **Level 2: Grand Ballroom**
Theme 1: *Gaps in Glomerular Disease Clinical Trials: Where Are We Today?* Sponsored by Walden Biosciences			
11:15 AM - 11:25 AM	Introduction	**Shikha Wadhwani**	GICC **Level 2: Grand Ballroom**
11:30 AM - 12:15 PM	GD Trials Today: Updates from 2025 & 2026 Meetings *Moderator:* **Liz Lightstone**	**Jonathan Barratt** **Brad Rovin** **Marina Vivarelli**	GICC **Level 2: Grand Ballroom**
12:15 PM - 12:30 PM	QA/Discussion		GICC **Level 2: Grand Ballroom**
12:30 PM - 1:30 PM	**Lunch**		GICC **Level 1: West Foyer**
Theme 2: *Past Lessons and Future Vision (Part A)*			
1:30 PM - 1:35 PM	Introduction	**Kirk Campbell**	GICC **Level 2: Grand Ballroom**
1:35 PM - 2:20 PM	From the Rearview Mirror to the Road Ahead for GD Trials *Moderator:* **Kirk Campbell**	**Hiddo Heerspink** **Vlado Perkovic** **Katherine Tuttle**	GICC **Level 2: Grand Ballroom**
2:25 PM - 3:00 PM	Lessons Learned in GD Trials: LN, IgAN, C3G, MN *Moderators:* **Daniel Gale, Marina Vivarelli**	**Ana Malvar** **Patrick Nachman** **Carla Nester** **Sean Barbour**	GICC **Level 2: Grand Ballroom**
3:00 PM - 3:20 PM	QA/Discussion		GICC **Level 2: Grand Ballroom**
3:20 PM- 3:50 PM	**Coffee/Afternoon Snack**		GICC **Level 2: Grand Ballroom Foyer**

Day 1: Friday, November 13, Continued

Galveston Island Convention Center - GICC

Time	Session	Speakers	Location
Theme 3: *Emerging Biomarkers & Treatment Targets in GD Clinical Trials*			
3:50 PM - 3:55 PM	Introduction	**Alessia Fornoni**	GICC **Level 2: Grand Ballroom**
4:00 PM - 4:08 PM	Biomarkers as Potential Endpoints that Reflect How A Patient Feels, Functions and Survives *Moderators:* **Alessia Fornoni, Laura Barisoni**	**Laura Mariani**	GICC **Level 2: Grand Ballroom**
4:08 PM - 4:16 PM	A Biomarker Today?… an Endpoint Tomorrow? Anit-nephrin Autoantibodies	**Nicola Tomas**	GICC **Level 2: Grand Ballroom**
4:16 PM - 4:24 PM	Neutralizing suPAR in Glomerular Disease: From Pathogenic Mechanism to a Therapeutic Phase 2 Trial	**Alexander Duncan**	GICC **Level 2: Grand Ballroom**
4:24 PM - 4:32 PM	Targeting Innate Immune Pathways in Glomerular Disease: Current Clinical Trials and Emerging Therapies	**Timothy Niewold**	GICC **Level 2: Grand Ballroom**
4:32 PM - 4:40 PM	Incorporating Gene Delivery to the Podocyte in GD Trials	**Alice Brown**	GICC **Level 2: Grand Ballroom**
4:40 PM - 4:50 PM	The Future is Here: Cellular Therapy and Bispecific Antibodies for GD	**Jonathan Hogan**	GICC **Level 2: Grand Ballroom**
4:50 PM - 5:15 PM	Q&A/Discussion		GICC **Level 2: Grand Ballroom**
5:15 PM - 6:00 PM	ROUNDTABLE - Voice of VCs: Translating Science into Therapeutics *Moderator:* **Vineet Gupta**	**Sahir Ali** **Mohsin Khan** **Michael Torres**	GICC **Level 2: Grand Ballroom**
6:30 PM - 7:30 PM	**Networking Reception**		San Luis Resort **Pool Deck**
7:30 PM - 9:30 PM	**Participant Dinner**		San Luis Resort **Grand Ballroom**

Day 2: Saturday, November 14 — Galveston Island Convention Center - GICC

Time	Session	Speakers	Location
7:00 AM - 8:25 AM	**Breakfast**		GICC **Level 1: West Foyer**
Continuing with Theme 2: *Past Lessons and Future Vision (Part B)*			
8:30 AM - 8:35 AM	Day 2 Welcome	**Shikha Wadhwani**	GICC **Level 2: Grand Ballroom**
8:35 AM - 8:40 AM	Introduction	**Meg Jardine**	GICC **Level 2: Grand Ballroom**
8:40 AM - 8:55 AM	Integrating Mechanistic Biopsies into GD Trials *Moderators:* **Meg Jardine, Rafael Kramann**	**Matthias Kretzler**	GICC **Level 2: Grand Ballroom**
8:55 AM - 9:10 AM	Leveraging Risk Prediction Tools for Stratification at Randomization	**Sean Barbour**	GICC **Level 2: Grand Ballroom**
9:10 AM - 9:25 AM	Platform Trials in GD	**Suceena Alexander**	GICC **Level 2: Grand Ballroom**
9:25 AM - 9:40 AM	Sequential Design and Treatment Combinations for GD Trials	**Hiddo Heerspink**	GICC **Level 2: Grand Ballroom**
9:40 AM - 9:50 AM	QA/Discussion		GICC **Level 2: Grand Ballroom**
9:50 AM - 10:05 AM	Addressing Unmet Needs in Peds Trials: Extrapolation and the SGTL2i Success Story *Moderator:* **Myda Khalid**	**Louise Oni**	GICC **Level 2: Grand Ballroom**
10:05 AM - 10:20 AM	Addressing Unmet Needs in Post-Transplant Recurrent GD Trials	**Priya Verghese**	GICC **Level 2: Grand Ballroom**
10:20 AM - 10:35 AM	QA/Discussion		GICC **Level 2: Grand Ballroom**
10:35 AM- 11:00 AM	**Coffee/Morning Snack**		GICC **Level 2: Grand Ballroom Foyer**
Theme 4: *Regulatory Advances*			
11:00 AM - 11:05 AM	Introduction	**Barbara Gillespie**	GICC **Level 2: Grand Ballroom**
11:10 AM - 11:40 AM	ROUNDTABLE - Voice of the FDA: What Keeps Us Up At Night? *Moderators:* **Brendon Neuen, Brad Rovin**	FDA Nephrologist from CDER*: **Nadia Chaudhri** **Austin Hu** **Rekha Kambhampati** **Kirtida Mistry** **Aliza Thompson** Former CBER^ nephrologist: **Anam Tariq**	GICC **Level 2: Grand Ballroom**

Day 2: Saturday, November 14, Continued

Galveston Island Convention Center - GICC

Time	Session	Speakers	Location
11:40 AM - 12:00 PM	QA/Discussion		GICC **Level 2: Grand Ballroom**
12:00 PM - 12:30 PM	Going Back In Time: Should the TESTING Trial Proceed? Casting the Last Vote of the DSMB	**Adeera Levin** **Vlado Perkovic**	GICC **Level 2: Grand Ballroom**
12:30 PM - 12:40 PM	QA/Discussion		GICC **Level 2: Grand Ballroom**
12:40 PM - 1:40 PM	**Lunch**		GICC **Level 1: West Foyer**
1:40 PM - 2:15 PM	Still Tried and True Endpoints? eGFR, Albuminuria, Proteinuria *Moderators:* **Alex Mercer, Abigail Smith**	**Tom Greene** **Hiddo Heerspink** **Lesley Inker**	GICC **Level 2: Grand Ballroom**
2:20 PM - 2:30 PM	Hierarchical Composite Endpoints, from Cardiology trials…to GD trials ?!	**Lesley Inker**	GICC **Level 2: Grand Ballroom**
2:30 PM - 2:40 PM	Clinical Outcomes Assessment as Endpoints: PREPARE-NS	**Eloise Salmon**	GICC **Level 2: Grand Ballroom**
2:40 PM - 3:10 PM	International GD Trialists' Response & QA *Moderator:* **Jonathan Barratt**	**Suceena Alexander** **Daniel Gale** **Ana Malvar** **Jule Pinter** **Heather Reich**	GICC **Level 2: Grand Ballroom**
3:10 PM - 3:30 PM	**Coffee/Afternoon Snack**		GICC **Level 2: Grand Ballroom Foyer**
3:30 PM - 4:15 PM	ROUNDTABLE: The Future of Kidney Brain Health *Moderator:* **Jochen Reiser**	**Mikele Epperly** **Mitch Elkind** **Peter McCaffrey**	GICC **Level 2: Grand Ballroom**
4:15 PM - 5:30 PM	**Poster Sessions & Networking**		GICC **Galleon Room**

*CDER= Center of Drug Evaluation and Research
^CBER= Center for Biologics Evaluation and Research

Day 3: Sunday, November 15 — Galveston Island Convention Center - GICC

Time	Session	Speakers	
7:30 AM - 8:55 AM	**Breakfast**		GICC **Level 1: West Foyer**
Theme 5: *Breaking Barriers for Successful Trial Recruitment & Execution*			
9:00 AM - 9:05 AM	Introduction	**Josh Tarnoff**	GICC **Level 2: Grand Ballroom**
9:05 AM - 9:15 AM	Voice of the Patient *Moderator:* **Josh Tarnoff**	**Jemila Alharazim**	GICC **Level 2: Grand Ballroom**
9:15 AM - 9:25 AM	GD Centers of Excellence	**Tobias B. Huber** **Ali Poyan Mehr**	GICC **Level 2: Grand Ballroom**
9:25 AM - 10:10 AM	ROUNDTABLE- Voice of the Clinical Trial Village: Improving Recruitment & Execution (and Workgroup announcement) *Moderators:* **Barbara Gillespie, Josh Tarnoff**	**Meg Jardine** **Sreedhar Mandayam** **Jennifer McKenzie** **Kristin Nabors** **Marina Vivarelli**	GICC **Level 2: Grand Ballroom**
10:10 AM - 10:35 AM	From Trial Challenges to Trial Solutions *Moderator:* **Shikha Wadhwani**	**Erika Allred** **Sweta Sinha** **William Smoyer**	GICC **Level 2: Grand Ballroom**
10:35 AM - 11:00 AM	**Coffee Break**		GICC **Level 2: Grand Ballroom Foyer**
11:00 AM - 11:45 AM	Late Breaking Research *Moderators:* **Prabir Roy-Chaudhury, Sydney Tang**	**TBA**	GICC **Level 2: Grand Ballroom**
11:45 AM - 12:30 PM	ROUNDTABLE- Voice of Pharma's C Suite: What Keeps Us Up At Night *Moderator:* **Uptal Patel**	**Rob Brenner** **Jula Inrig** **Jiahua Li**	GICC **Level 2: Grand Ballroom**
12:30 PM - 12:45 PM	Awards & Closing	**Tobias B. Huber**	GICC **Level 2: Grand Ballroom**
12:45 PM - 2:15 PM	**Farewell Lunch** ***Boxed lunch options available.***		GICC **Level 1: West Foyer**

Clinical Trials Summit Speaker List

Suceena Alexander
Christian Medical College Vellore

Jemila Alharazim
Patient

Sahir Ali
Modi Ventures

Erika Allred
Natera

Laura Barisoni
Duke University

Sean Barbour
The University of British Columbia

Jonathan Barratt
University of Leicester

Rob Brenner
Vera Therapeutics

Alice Brown
Purespring Therapeutics

Kirk Campbell
University of Pennsylvania

Nadia Chaudhri
CDER FDA Nephrologist

Prabir Roy-Chaudhury
University of North Carolina

Alexander Duncan
Walden Biosciences

Mitch Elkind
American Heart Association, Columbia University

Mikele Epperly
University of Texas Medical Branch

Alessia Fornoni
University of Miami

Daniel Gale
University College London

Barbara Gillespie
ISGD, University of North Carolina

Tom Greene
University of Utah Health

Vineet Gupta
University of Texas Medical Branch

Hiddo Heerspink
University Medical Center Groningen

Jonathan Hogan
Cabaletta Bio

Austin Hu
CDER FDA Nephrologist

Tobias B. Huber
ISGD, University Medical Center Hamburg-Eppendorf

Lesley Inker
Tufts University School of Medicine

Jula Inrig
Travere Therapeutics

Meg Jardine
The University of Sydney

Rekha Kambhampati
CDER FDA Nephrologist

Myda Khalid
Riley Hospital for Children, Indiana University School of Medicine

Mohsin Khan
Fortress Biotech

Brittan Kopittke
University of North Carolina

Rafael Kramann
Rheinisch-Westfälische Technische Hochschule, Aachen University

Matthias Kretzler
University of Michigan

Adeera Levin
University of British Columbia, Providence Health Care

Jiahua Li
Vertex Pharmaceuticals

Liz Lightstone
Imperial College London

Ana Malvar
University of Buenos Aires

Sreedhar Mandayam
UT MD Anderson Cancer Center

Laura Mariani
University of Michigan

Kedar Mate
Cornell, Qualified Health

Peter McCaffrey
University of Texas Medical Branch

Jennifer McKenzie
Boehringer Ingelheim

Ali Poyan Mehr
Kaiser Permanente Bernard J. Tyson School of Medicine

Alex Mercer
JAMCO Pharma Consulting

Kirtida Mistry
CDER FDA Nephrologist

Kristin Nabors
Johns Hopkins University

Patrick Nachman
University of Minnesota

Carla Nester
University of Iowa

Brendon Neuen
The George Institute for Global Health

Timothy Niewold
Hospital for Special Surgery

Louise Oni
UCL & University of Liverpool

Uptal Patel
Estuary Bio

Vlado Perkovic
University of New South Wales Sydney

Jule Pinter
University Medical Center Hamburg-Eppendorf

Jochen Reiser
University of Texas Medical Branch

Brad Rovin
The Ohio State University

Eloise Salmon
University of Michigan

Sweta Sinha
iTrials

Abigail Smith
Northwestern University

William Smoyer
Nationwide Children's Hospital

Sydney Tang
The University of Hong Kong

Anam Tariq
Former CBER FDA Nephrologist

Josh Tarnoff
NephCure

Aliza Thompson
CDER FDA Nephrologist

Nicola Tomas
University Medical Center Hamburg-Eppendorf

Michael Torres
CrossBridge Bio

Katherine Tuttle
University of Washington, Providence Medical Research Center

Priya Verghese
Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern University

Marina Vivarelli
Bambino Gesù Children's Hospital, IRCCS

Shikha Wadhwani
University of Texas Medical Branch

The Honorable Randy Weber
U.S. Representative, Texas's 14th Congressional District