LUNG GVHD CONSORTIUM

Thursday, 29 October 2026
Lung GVHD Consortium Monthly Meeting
8:30 – 9:30 AM PDT | 11:30 – 12:30 PM EDT | 5:30 – 6:30 PM CEST
Meeting via Zoom (not recorded)

AGENDA

Announcements

- Upcoming meetings and case discussions

High level recap of Geneva Conference

- Day 1 / Day 2 Key Takeaways
  - Definition / Diagnostic criteria updates and next steps
- Day 3 Clinical Trials
  - Follow-up surveys from the Breakout sessions:
    Group 3: Agents to Test (presented by Dr Catherine Lee, FHCC)
    Group 4: Correlative Studies (presented by Dr. Sean Agbor-Enoh, NIH/NHLBI)

Next meeting: Thursday 19 November 2026.

MEETING MINUTES

Announcements

- Tandem 2026 Orlando
  - 2/16 Ancillary Meeting Tues (TBD)
    - Focus on Response Criteria and Clinical Trials
  - 2/17 RVI and BOS Scientific Talk for ID Track (GSC)
  - 2/19 President's Spotlight Session on Lung cGVHD (Bruce Blazar, Joe Hsu, GSC)
- ATS 2026 New Orleans 5/14-19
- CHEST 2027 Vancouver

High level recap of Geneva Conference
Dates: 23-25 September 2026
In person attendance: 157
Online attendance: 25-30 daily
Video highlight: https://youtu.be/MYvvng1_jf4

Day 1: Pathogenesis
Synthesize preclinical understanding of the pathogenesis of BOS that occurs in the context of allogeneic hematopoietic cell transplant and identify translatable targets and key priorities for preclinical investigation

Key Takeaways

- Airways cGVHD is a pan-airways process; the **anatomic and cellular specificities of small airways** dictate the clinical and physiologic consequences.
- Early and ongoing injurious infectious and noninfectious **triggers** and **loss of airway epithelial progenitor cells** orchestrate the multifaceted **chronic alloimmune responses** (B cells, TLS, profibrotic macrophages,

Tfh) that lead to lung fibrosis.
- The **lung endothelium** is likely underrecognized as an instigator of post-HCT lung injury of all forms, including BOS, which is supported by clinical observation of DLCO impairment.
- A key and **critical insight** from preclinical models of transplant fibrosis: there are **different forms of collagen that can broken down** by targeting non-canonical pathways.
- We have the **translational tools** (murine models, lung organoids, HPLS, omics) and **novel insights** from cGVHD, CLAD, IPF, bronchiectasis, to develop biomarkers (e.g. cfDNA) and rationale **targeted therapies** for BOS and lung cGVHD.

Next Steps
- Manuscript draft
- Specific projects
    - cfDNA and biomarker discovery
    - LT and BOS endotyping (BAL)
    - Preclinical testing
    - Ongoing multicenter natural history cohort
    - Consideration of therapeutic agents: pulmonary antifibrotics, DPP-1 inhibitors, CCSP repletion, etc.

<u>Day 2: Updating the NIH Definition of BOS</u>
Derive a consensus revision of the HCT-BOS diagnostic criteria and conceptual framework for defining lung chronic GVHD

Key Takeaways
- Because lung cGVHD involves more than just airways, physiology and diagnostic imaging needs to be interpreted accordingly in the **context of alternative etiologies** (including active infection) aided by **multidisciplinary discussions**.
- Our conventional tools to measure physiology are limited by inherent imprecision, feasibility, and interpretation and thus we need to develop and employ **novel diagnostic technologies**.
- While histology is not required for a clinical diagnosis of lung cGVHD, **clinico-pathologic correlations** always provide valuable insights.
- With concerted efforts at PFT **implementation and longitidinal assessment**, we should be able to improve early recognition of lung cGVHD. This is particularly important in light of evolving HCT practices.
- Under a more inclusive diagnostic definition, we can aim for more accurate **phenotyping and endotyping** of lung cGVHD.

Next Steps
- Public comment period ends tomorrow 10/30
- Delphi TBD
- Primary Manuscript submission no later than 1/2027
- Additional manuscripts
    - Implementation Group x 2 ◊ ready to submit now
- RESEARCH
    - Application of new diagnostic criteria to multicenter cohort (Yadav, Sharifi, Adderley, et al)
    - Multicenter natural history cohort and Common Protocol
    - Ongoing work with alternative diagnostic modalities

LUNG GVHD CONSORTIUM

Day 3: Clinical Trials
Establish an ideal clinical trial design and identify clinical trial readiness gaps for Lung GVHD after HCT

Highlights
- Mr. Guy Livneh and Patient Perspective
- Industry Panel
    - 'Be creative' – Jason Chien
- Breakout group report out
- White Board Ideal Clinical Trial (Hackathon)

Breakout Groups
- Trial Design: Greg Yanik and Jamie Todd
- Inclusion and Endpoints: Najla El Jurdi and GSC
- Agents to Test: Catherine Lee and Bruno Crestani
- Correlative Studies: Sean Agbor-Enoh and Jose Antonio Perez Simon
- Recruitment and Retention: Helene Schoemans and Danielle Stahlbaum

Key Takeaways
- The **patient voice** is critical for all aspects of trial design including response criteria, endpoints, recruitment and retention.
- Industry and regulatory **partners** are ready to work with key stakeholders.
- Natural history studies, biomarker discovery, and interventional trials should occur **in tandem**.
- There are off-the-shelf as well as unmarketed agents that can be tested in a controlled fashion under a **platform design**.
- Preventing and reversing the pulmonary impairment of lung cGVHD still comes back to our understanding of **natural history and pathogenesis**.

- The breakout session discussions served as a **starting point** for ongoing discussions with key stakeholders to move forward with **creative solutions** and innovative clinical trials for lung cGVHD.

Breakout groups 3 and 4: Agents to test and Correlative Studies
- Catherine Lee MD
- Sean Agbor-Enoh MD PhD

In addition to the Key Takeaways from Days 1, 2, and 3 of Geneva (see Slide Deck), we heard brief presentations from post-Geneva follow-up work from Day 3 Clinical Trials Breakout Groups 3 and 4. Sean Agbor-Enoh presented the preliminary results from the Correlative Studies survey that he and Jose Antonio Simon Perez crafted with their group on which correlative biomarkers should be prioritized for use in clinical trials. There were 47 respondents to their survey. There was broad consensus for the use of chest CT imaging techniques including PRM as a potential endpoint / biomarker. There are no validated serologic biomarkers for BOS / lung cGVHD; there was broad consensus that serologic biomarkers are largely exploratory. More details will be shared about the survey including the respondent characteristics and which biomarkers could be prioritized in a clinical trial.

Then Catherine Lee of Breakout Group 3 Agents to Test shared the results of her intragroup survey which had 9/13 respondents. Key messages from the survey included that the goal of first line therapy for BOS should be

improvement in the FEV1. There was unanimous agreement on prioritizing agents (or combinatorial approaches) that had both inflammatory and antifibrotic properties. Respondents were most interested in testing rovacitinib, a novel agent in development by Sanofi, then nerandomilast, which is FDA-approved for IPF, and third, axatilimab. Priority factors for choosing a drug included safety and tolerability as well as strength of the data in BOS, among other factors including mechanism and feasibility / cost.

ATTENDEES

Name	Organization
Ajay Sheshadri, M.D., MSCI	MD Anderson Cancer Center
Ann Bergeron, M.D., Ph.D.	Hôpitaux Universitaires de Genève
Annie Im	University of Pittsburgh
Carson Moss	Stanford University
Catherine Lee, MD, MS	Fred Hutchinson Cancer Center
Corey Cutler, M.D., MPH	Harvard/Dana-Farber Cancer Institute
Danielle Stahlbaum, MD	University of Michigan Health
David Epstein, M.D.	Stanford University
Einat Shmueli	Schneider Children's Medical Center of Isreal
Emmanuel Mongodin	NIH, NHLBI
Geoff Cuvelier	Alberta Children's Hospital
Gianluca Martini	Fondazione IRCCS Policlinico San Matteo
Guang-Shing Cheng, M.D.	Fred Hutchinson Cancer Center
Guy Livneh	Patient Advocate, Stanford
Hélène Salvator, M.D.	Université Versailles Saint Quentin-Paris Saclay
Hrish Kulkarni	University of California, Los Angeles
Irene Defrancesco	Fondazione IRCCS Policlinico San Matteo
Jeffrey Man, M.D.	University Health Network and Mount Sinai Hospital
Jeffrey Sturek, M.D.	University of Virginia School of Medicine
Jerry Weinhouse, MD	Brigham and Women’s Hospital
Jonathan Rayment	BC Children’s Hospital
Jose A. Perez Simon	Virgen del Rocío University Hospital
Katrin Hostettler, MD	University Hospital Basel
Liz Curtis	Fred Hutchinson Cancer Center
Louise Bondeelle, M.D., Ph.D.	University of Geneva
Matt Zinter, M.D.	University of California San Francisco
Parvathi Ranganathan	Ohio State University
Patrick Mellors, M.D.	Geisel School of Medicine, Dartmouth
Raghu Loganathan, MD, ATSF, FCCP, FCCM	Memorial Sloan Kettering Cancer Center
Samuel Goldfarb	University of Minnesota
Saskia Bos	University Hospitals Leuven
Sean Agbor-Enoh	NHLBI-NIH

Steven Pavletic, MD, MS	Center for Cancer Research, National Cancer Institute
Veronique Houdouin	Université de Paris Cité
Xiaoping (Amanda) Wu, MD, MS	Loyola University Medical Center

Guest List/Not in Attendance

Name	Organization
Alicja Sadowska-Klasa, M.D.	Fred Hutchinson Cancer Center
Alpana Waghmare, M.D.	Fred Hutchinson Cancer Center
Amir Bar-Shai, MD	Tel Aviv Sourasky Medical Center
Assem Ziady	Cincinnati Children's Hospital
Austin Chen, M.D.	Fred Hutchinson Cancer Center
Avanti Gulhane	Fred Hutchinson Cancer Center
Bethany Moore, Ph.D.	University of Michigan
Carla Kim	Boston Children’s Hospital
Charles Dela Cruz, M.D. Ph.D.	University of Pittsburgh
Cheryl Sung	Fred Hutchinson Cancer Center
Cissy Si, M.D.	Stanford University
Clare Sander, MD	Cambridge University Hospitals NHS Foundation Trust
Craig Galban, Ph.D.	University of Michigan
Daniel Wolff, MD	University Hospital Regensburg
David O'Dwyer, MB BCH BAO, Ph.D.	University of Michigan
Davide Piloni	Fondazione IRCCS Policlinico San Matteo
Dean Lee, MD	Nationwide Children’s Hospital
Emily Wyse	Fred Hutchinson Cancer Center
Emma Kundracik	Case Western Reserve University and Cleveland Clinic
Federica Briganti	Fondazione IRCCS Policlinico San Matteo
Felipe Soto, MD	Indiana University
Francine Kelly	Duke University School of Medicine
Giovanna Lucchini, MD	IRCCS San Gerardo dei Tintori di Monza
Gordon Smiknak, MD	University of Virginia
Gregory Yanik, M.D.	University of Michigan
Hemang Yadav, MBBS	Mayo Clinic
Husham Sharifi, M.D.	Stanford University
Iskra Pusic, MD, MSCI	WashU Medicine, St. Louis
Jamie Lynn Todd, M.D.	Duke University School of Medicine
Jane Turner, M.D.	McMaster University
Jeong Uk Lim	The Catholic University of Korea
Jeonguk Lim, MD	MD Anderson Cancer Center
Joe Hsu, M.D.	Stanford University
Juliana Silva	Great Ormond Street Hospital, London
Julie Boiko, M.D., MS	Fred Hutchinson Cancer Center

LUNG GVHD CONSORTIUM

Ken Cooke, M.D.	Johns Hopkins Medicine
Kevin Ho, MD	Ohio State University Wexner Medical Center
Kirk Schultz, MD, PhD	University of British Columbia, Vancouver
Kirsten Williams, M.D.	Emory University School of Medicine
Kyle Brownback, M.D., FCCP	University of Kansas Medical Center
Laveena Chhatwani, M.D.	Stanford University
Madelyn Peha, M.D.	Lurie Children's Hospital
Maggie Guerrero, MSN, RN, ARNP	Fred Hutchinson Cancer Center
Margherita Paschini, PhD	Boston Children’s Hospital
Mark Barash, DO	Medical College of Wisconsin
Matthew Hensley, M.D., MPH	University of Pittsburgh Medical Center
Merav Avital	Tel Aviv Sourasky Medical Center
Michael Boeckh, M.D., Ph.D.	University of Washington
Mike Vo	Fred Hutchinson Cancer Center
Mirza Haider Ali, MD	Northside Hospital
Muhammad Faizyab Ali Chaudrary	University of Alabama School of Medicine
MyLinh Duong, M.D.	McMaster University
Najla El Jurdi, MD	Center for Cancer Research, National Cancer Institute
Nicola Adderley, M.D.	University of Calgary
Nicola Polverelli	Fondazione IRCCS Policlinico San Matteo
Nicole Scovil	Fred Hutchinson Cancer Center
Ophir Freund, MD	Tel Aviv Sourasky Medical Center
Paul Carpenter, MBBS	Fred Hutchinson Cancer Center
Rabi Hanna, MD	Cleveland Clinic
Reid Eggleston	Mayo Clinic - Rochester
Rene Bermea, MD	Massachusetts General Hospital/Harvard Medical School
Said Chaaban, M.D.	University of Nebraska Medical Center
Santhosh Thyagu, MD	Ottawa Hospital
Sarah Huda Omar	Stanford University
Sarah Johnson	Patient FHCC/UWMC
Seth Rotz, MD	Cleveland Clinic
Shubha Srinivas	Inova Schar Cancer Institute
Sophie Paczesny, M.D., Ph.D.	Medical University of South Carolina
Stella Davies, MBBS, PhD, MRCP	Cincinnati Children's Hospital Medical Center
Stephanie Lee, M.D., MPH	Fred Hutchinson Cancer Center
Stephanie Sarantopoulos, MD, PhD	Duke University
Stephen Kirkby, MD	Nationwide Children’s Hospital
Sudhakar Pipavath, M.D.	University of Washington Medical Center
Sunita Mulpuru, MD	Ottawa Hospital
Valentina Vertui	Fondazione IRCCS Policlinico San Matteo
Wei Wu	University of Washington

Xiaofeng Zhou	University of Michigan
Yeheun Cho	Fred Hutchinson Cancer Center
Yu Kuang (Julie) Lai	Stanford University
Zack DeFilipp	MGH and Harvard Medical School

ADJOURN