The Lung GVHD Consensus Project			
Days	**Sep 23** **PATHOGENESIS OF LUNG GVHD**	**Sep 24** **UPDATING THE NIH DEFINITION OF BOS**	**Sep 25** **CLINICAL TRIALS FOR LUNG GVHD**
Goals	Focus on translational research with applications to patients: 1) Synthesize preclinical understanding of the pathogenesis of BOS that occurs in the context of allogeneic hematopoietic cell transplant, 2) Identify translatable targets 3) Identify key priorities for preclinical investigation	To derive a consensus revision of the HCT-BOS definition based on up-to-date evidence	Establish an ideal clinical trial design and identify clinical trial readiness gaps for Lung GVHD after HCT
Times			
0800		**Introduction**: Why an NIH definition for lung GVHD? The Rationale for a Revision (30) Chairs: Cheng, Bergeron, Pavletic, Wolff • From BO to BOS: Defining Lung GVHD (**Bergeron**, 5) • Historical context of the lung chronic GVHD definition and response criteria (**Pavletic**, 5) • Considerations of practice heterogeneity on the landscape of cGVHD and lung disease (**Wolff**, 10) • The diagnostic framework and introduction of working proposal (**Cheng**, 10)	**Introduction**: • Summary of Day 1 and Day 2 (**Hsu and Cheng**, 5) • Why we need BOS-specific clinical trials (**Bergeron**, 10)
0815			**Session 1.** Current therapeutic landscape for HCT-BOS (75) Chair: Bergeron / Hsu • Guidelines versus the reality (**Schoemans,** 15) • FDA-approved cGVHD agents and BOS trials: a pulmonologist's perspective (**Bergeron**, 15) • Antifibrotics and the Pulmonary Drug pipeline (**Hostettler**, 15) • Alternative therapies (e.g. ECP) and cGVHD drug pipeline (**Wolff**, 15) • Q&A / Panel Discussion (15)
0830	Welcoming participants	**Session 1.** Diagnostic Elements: Physiology[1](60) Chairs: Bergeron / Cheng • Basics of PFTs: spirometry, lung volumes, DLCO, and current interpretative strategies (**Turner**, 15) • Patterns of airflow obstruction, small airways disease, and reversibility relevant to clinical BOS (**Weinhouse**, 15) • Alternatives to conventional PFTs, e.g oscillometry, MBW [1] (**Robinson** 15) • Gaps, controversies, recommendations and discussion (**Cheng/Subgroup**, 15)	
0845	Welcoming Pr Antoine Geissbuhler, Dean of the University of Gene		
0900	**Introduction**: Building on the ATS Research Statement (**Cheng**, 10)		
0910	**Session 1:** Knowledge Review (15 min each, 5 min questions, 60 min total) • Airway epithelial / endothelial injury (**Todd**) • Lung specificities of macrophages, cellular immunity, and alloimmune mechanisms (**Boiko**) • Viral infections and BOS development (**Bondeelle**)		
0930		**Session 2**: Diagnostic Elements: Chest imaging [2] Chair: Sharifi • Chest imaging correlates of airflow obstruction / small airways impairment, including CXR, CT, MRI (**Hamer** 20) • Novel approaches to chest imaging and e.g. MRI, qCT [2] (**Yanik** 20) • Gaps, controversies, recommendations and discussion (**Sharifi/Subgroup**, 20)	**Session 2**: Clinical trial partnerships (Industry Panel) (45) Chair: Wolff The logistics of establishing multicenter / international collaborations US/EU (Jason Chien, Therakos, Buto Corp, Incyte pending, FDA/EMA/NIH representatives)
1010	Coffee Break		
1015			Coffee Break
1030	**Session 2**: Knowledge Review (15 min each, 5 min questions, 60 min total)	Coffee Break	**Session 3:** Clinical trial design elements (90) Chair: Cheng
1045	• Role of infection, microbiome in post-HCT (**Zinter**) • Dysbiosis, metabolomics in lung GVHD (**Michonneau**) • Cell free DNA in lung transplant (**Agbor-Enoh**)	**Session 3**: Diagnostic Elements: Necessary conditions and exclusions[3] (60) Chair: Sheshadri • Pro/Con: Exclusion of infection and the need for bronchoscopy (Pro: **Sander**, Con: TBD, 20) • Requirements for clinical context (e.g. other cGVHD) and the need for histology (**C. Lee**, 20)	• Trial designs for interstitial lung diseases: adaptive, umbrella / basket (**Toby Maher**, 20) • RCT or not? A matter of equipoise and alternatives (TBD, 20) • BOS / Lung GVHD endpoints: use of continuous measures and PROs (Gooley, 20) • Disease stratification (stages and phenotypes) and statistical concerns (Chevret, 20)
1130	Coffee Break		
1140	**Session 3**: Pro/con "Idiopathic pneumonia syndrome is a risk factor for lung GVHD" Pro: **Cooke**, Con: **Sheshadri.** (15 min presentation/ 20 min panel discussion, 50 minutes total)		

	Address curated questions for speakers e.g., How can we investigate this in human studies?	• Gaps, controversies recommendations and discussion (**Sheshadri**/Subgroup, 20)	• Q&A / Discussion (10 minutes)
1145		**SUMMARY** of Revision Part 1 (**Cheng, Sharifi, Sheshadri**, 15)	
1200		Lunch	Lunch
1230	Lunch		
1300		**Session 4.** Considerations for Special Populations and Scenarios[5] (75) Chair: Williams • Consideration of preexisting lung disease and the impact of aging on lung function (**Yadav**, 15) • The impact of growth on lung function [5] (**Shanthikumar**, 15) • Specific Pediatric Considerations for lung function testing, chest imaging, and invasive diagnostic testing [1,2,5] (**Davies,** 15) • Recommendations for minimum diagnostic criteria, if no diagnostic testing can be obtained (including low resource setting) [5] (**Williams**/Subgroup, 15) • Discussion (15)	**Session 4:** Clinical trial design brainstorming session • Breakouts to brainstorm 1) trial design; and 2) agents to test; 3) gaps in clinical trial readiness (30 minutes) • Small group reports and discussion (30 minutes)
1330	**Session 4:** Panel discussion: Pathways of Fibrosis 20 min each, 70 total) • ILD: **Bruno Crestani** • Lung Transplant: **Belperio** • BOS/cGVHD: **Blazer** • Discussion (10+)		
1400			**Session 5:** Plenary Discussion: White Board proposal for the Ideal Clinical Trial and next steps (90 minutes)
1415		**Session 5**. Mixed phenotypes and Non-BOS Lung entities: GVHD or not GVHD[4] (90) Chairs: Sturek / Bergeron • Pro/Con Bronchiectasis: a consequence of BOS, or its own lung GVHD entity? (Epstein / Bergeron, 20) • Mixed physiology and non-parenchymal restriction (**Sturek** 15) • Organizing pneumonia and Interstitial lung disease entities (**Lai**, 15) • Pro/Con: Applying CLAD-RAS criteria to HCT Lung GVHD? (Pro: **S. Bos,** Con: **Bergeron**, 20) • Recommendations and discussion: Include non-BOS as GVHD, and which entities? (Sturek / Bergeron, 20)	
1440	Session 4: The role of large airway pathology in BOS (20 min each, 70 total) • Are large airways involved in BOS? (**Bergeron**) • Prevalence of bronchiectasis after cellular therapies (**Epstein**) • Non-CF bronchiectasis novel treatments and future directions (**Barker**) • Discussion (10+)		
1530			**SUMMARY and ADJOURN Day 3 and Meeting** (Cheng / Bergeron)
1545		Coffee Break	
1550	Coffee Break		
1600			
1610	Session 6: Translational approaches to studying lung GVHD (20 min each, 70 total) • Murine models of OB and transplant pulmonary fibrosis (**Hsu**) • BOS lung organoids (**Kim Lab)** • Ex vivo human lung samples BOS vs. CLAD (**Mellors**) • Discussion (10)	**Session 6.** Implementation Panel[6] (60) The discussion will be prompted by the chairs introducing each question and posing to panelists Chair: Daniel Wolff* Panelists: Yves Chalandon, John Murray, Danielle Stahlbaum, Sam Goldfarb, Paul Carpenter, Najla El-Jurdi Topics: 1) How to implement definition in the clinic with HCT physicians,[6] 2) How to implement diagnostics and definition with pulmonary providers, 3) Considerations for the patient perspective, 4) How to validate proposed revision,[6] 5) Gaps, controversies and recommendations (Chairs)	

1700		**Session 7.** Plenary Discussion for Revision Recommendations and Next Steps (30)	
1720	**Session 7:** Plenary summary and discussion of next steps (**Paczesny/Hsu**) (30 min)		
1730		**ADJOURN DAY 2**	
1750	**ADJOURN Day 1**		