NIH 2020 Chronic GVHD Consensus
Project on Criteria for Clinical Trials

**AGENDA**

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| **Wednesday, November 18, 2020** |

**Session 1**

10:00 a.m. **Welcome and Introductions**

Steven Pavletic, M.D., Center for Cancer Research, NCI

 Brigitte Widemann, M.D., Center for Cancer Research, NCI

**Working Group 1: Report: Etiology and Prevention of Chronic GVHD**

Session Chair: Steven Pavletic, M.D., Center for Cancer Research, NCI

Moderator: Paul Martin, M.D., Fred Hutchinson Cancer Research Center

 Presenters: Stefanie Sarantopoulos, M.D., Ph.D., Duke University

Gerard Socie, M.D., Ph.D., St-Louis Hospital

10:15 a.m. **Overview of the Paper (20 minutes)**

Stefanie Sarantopoulos, M.D., Ph.D., Duke University

Gerard Socie, M.D., Ph.D., St-Louis Hospital

10:35 a.m. **Critique of the Paper (20 minutes) and response (15 minutes)**

 Reviewers: Nicolaus Kroeger, M.D., University of Hamburg

Ryo Nakamura, M.D., City of Hope Cancer Center

John Dipersio, M.D., Washington University

11:10 a.m. **Open discussion of the Paper (40 minutes)**

Live Q/A discussion is open to Working Group 1 panel and all participants.

11:50 Moderator summarizes themes and next steps (5 min)

11:55 Final comments by Chair (5 min)

12:00  **Adjourn**

12:00-1.00 p.m.Lunch

**Session 2**

1.00 p.m. **Introduction**

Chair: Kirk Schultz, M.D., University of British Columbia

Moderator: Stephanie Lee, M.D., Fred Hutchinson Cancer Research Center

**Working Group 2a: Report: Clinical Implementation and Early Diagnosis of Chronic GVHD**

Presenters: Carrie Kitko, M.D., Vanderbilt University

Corey Cutler, M.D., M.P.H, FRCPC, Dana Farber Cancer Institute

1:05 p.m. **Overview of the Paper (15 minutes)**

 Carrie Kitko, M.D., Vanderbilt University

Corey Cutler, M.D., M.P.H, FRCPC, Dana Farber Cancer Institute

1:20 p.m. **Critique of the Paper (20 minutes) and response (10 minutes)**

Reviewers: Mark Juckett, M.D., University of Wisconsin

George Chen, M.D., University of Rochester

Rafael Duarte, M.D., University Puerta de Hierro Majadahonda

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**Working Group 2b: Report: Preemptive Therapy of Chronic GVHD**Presenters: Joseph Pidala, M.D, Ph.D., Moffitt Cancer Center
 Geoffrey Hill, M.D., FRACP, FRCPA, Fred Hutchinson Cancer Research Center

1:50 p.m. **Overview of the Paper (15 minutes)**

Joseph Pidala, M.D, Ph.D., Moffitt Cancer Center

Geoffrey Hill, M.D., FRACP, FRCPA, Fred Hutchinson Cancer Research Center

2:05 p.m. **Critique of the Paper (20 minutes) and response (10 minutes)**

Reviewers: Franco Locatelli, M.D., University of Pavia

Areej El-Jawahri, M.D., Massachusetts General Hospital

Robert Soiffer, M.D., Dana Farber Cancer Institute

2:35-3.05 p.m. **Open discussion of the Papers (30 minutes)**

Live Q&A discussion is open to Working Group 2 panel and all participants.

3:05 Moderator summarizes themes and next steps (5 min)

3:10 Final comments by Chair (5 min)

3:15 **Adjourn**

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| **Thursday, November 19, 2020** |

**Session 3**

**Working Group 3: Report: Treatment of Chronic GVHD**

10.00 a.m. **Introduction**

Session Chair: Daniel Wolff, M.D., University of Regensburg

Moderator: Paul Martin, M.D., Fred Hutchinson Cancer Research Center

Presenters: Zachariah DeFilip, M.D., Massachusetts General Hospital,

Daniel Couriel, M.D., M.S., University of Utah,

Bruce Blazar, M.D., University of Minnesota,

Hildegard Greinix, M.D., University of Graz

10:05 a.m. **Overview of the Paper (20 minutes)**

Zachariah DeFilip, M.D., Massachusetts General Hospital,

Daniel Couriel, M.D., M.S., University of Utah,

Bruce Blazar, M.D., University of Minnesota,

Hildegard Greinix, M.D., University of Graz

10:25 a.m. **Critique of the Paper (20 minutes) and response (15 minutes)**

 Reviewers: Daniel Weisdorf, M.D., University of Minnesota

Keith Sullivan. M.D., Duke University

Catherine Lee, University of Utah

11:00 a.m. **Open discussion of the Paper (50 minutes)**

Live Q&A discussion is open to Working Group 3 panel and all participants

11:50 Moderator summarizes themes and next steps (5 min)

11:55 Final comments by Chair (5 min)

12:00 **Adjourn**

12:00 -1.00 p.m. Lunch

**Session 4**

1.00 p.m. **Introduction**

Session Chairs: Kirk Schultz, M.D., University of British Columbia

 Steven Pavletic, M.D., Center for Cancer Research, NCI

Moderator: Stephanie Lee, M.D., Fred Hutchinson Cancer Research Center

**Working Group 4: Report: Highly Morbid Forms of Chronic GVHD**

Presenters: Daniel Wolff, M.D., University of Regensburg

Sophie Paczesny, M.D., University of South Carolina

1:05 p.m. **Overview of the Paper (20 minutes)**

 Daniel Wolff, M.D., University of Regensburg

Sophie Paczesny, M.D., University of South Carolina

1:25 p.m. **Critique of the Paper (20 minutes) and response (15 minutes)**

Reviewers: Jose Antonio Perez-Simon, M.D., Instituto de Biomedicina de Sevilla

Doris Ponce, M.D. Memorial Sloan-Kettering Cancer Center

Andrew Harris, M.D., University of Utah

2:00 p.m. **Open Discussion of the Paper (50 minutes)**

Live Q&A discussion is open to Working Group 4 panel and all participants.

2:50 p.m. Moderator summarizes themes and next steps (5 min)

2:55 p.m. Final comments by Chair (5 min)

3:00 p.m. **Adjourn**

For post-conference comments and questions please email to:

CGVHD2020@mail.nih.gov

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| **Friday, November 20, 2020** |

**Session 5**

10.00 a.m. **Introduction**

Session Chairs: Steven Pavletic, M.D., Center for Cancer Research, NCI

 Paul Martin, M.D., Fred Hutchinson Cancer Research Center

**Industry Summit**

Presenters: Corey Cutler, M.D., M.P.H., FRCPC, Dana Farber Cancer Institute

Daniel Couriel, M.D., M.S., University of Utah

10:05 a.m. **Summit Goals**

10:15 a.m. **Conclusions of the NIH Working Groups discussion**

10:25 a.m. **Challenges and Plans for Improved Academia and Industry Collaboration**

10:45 a.m. **Open Discussion**

 Live Q&A discussion is open to all participants

12:00 p.m. **Adjourn**

12:00-1.00 p.m. Lunch

**Session 6**

Session Chairs: Stephanie Lee, M.D., Fred Hutchinson Cancer Research Center

 Kirk Schultz, M.D., University of British Columbia

**Patient Advocacy Summit**

Moderators: Meredith Cowden, M.A., LPCC-S, Cowden Foundation

Daniel Wolff, M.D., University of Regensburg

1:00 p.m. **Introduction and Goals**

1: 05 p.m. **Four NIH Consensus Working Group Presentation**

Presenters: Katie Schoeppner, M.S.W., LICSW, Be The Match

 Michelle Bishop, Ph.D., Coping with Cancer and Caregiving, LLC

 Susan Stewart, BMT InfoNet

 Meredith Cowden, M.A., LPCC-S, Cowden Foundation

 Peggy Burkhard, NbmtLINK

 Guy Bouguet, France Lymphome Espoir

 Christina Ferraro, C.N.P., Cleveland Clinic Foundation

 Chiara DeBiase, M.Sc., B.Sc., MCSP, Anthony Nolan

1:30 p.m. **Menti Test Survey**

Helene Schoemans, M.D., Ph.D., University Hospitals Leuven, KU Leuven, Leuven, Belgium

1:35 p.m. **Crucial Advocacy Topics**

 **Patient and Caregiver Education and Support**

Presenter: Katie Schoeppner, M.S.W., LICSW, Be The Match

1:50 p.m. **Neurocognitive and Psychosocial Impact**

Presenter: Susan Stewart, BMT InfoNet

2:05 p.m. **Survivorship and Long-Term Care**

Presenters: Naomi Pineda, Patient

 Christina Ferraro, C.N.P., Cleveland Clinic Foundation

2:20 p.m**. Menti Survey**

Helene Schoemans, M.D., Ph.D., University Hospitals Leuven, KU Leuven, Leuven, Belgium

2:35-3.00 p.m. **Open Discussion**

 Live Q&A discussion open to all participants

3.00-3.15 p.m. **Closing remarks**

 Meredith Cowden, M.A., LPCC-S, Cowden Foundation

For post-conference comments and questions please email to:

CGVHD2020@mail.nih.gov

**ABOUT THE MEETING**

This meeting is focused on four working group (WG) presentations of five documents aimed at moving the chronic GVHD field fundamentally forward while capitalizing on the achievements of the 2005 and 2014 consensus conferences. Sessions are designed to allow ample time for the discussion and live questions from the participants. Sessions will be recorded and available on the conference website for 30 days after the meeting.

**Methods**: Each working group was created to encourage global engagement in the topic. Groups worked individually to review the relevant literature and create the initial draft of the paper, which was reviewed and commented on by the Steering Committee. Two iterative rounds of comments from the Steering Committee were collected prior to the November 2020 Consensus Conference with appropriate manuscript revisions. Based on additional comments from independent external reviewers, conference participants and a 30-day post-conference public comment period, the papers will be further revised for the submission.

**PROJECT STEERING COMMITTEE MEMBERS**

**Chairs**: Steven Pavletic, M.D., M.S., National Cancer Institute; Stephanie Lee, M.D., M.P.H., Fred Hutchinson Cancer Research Center; Kirk Schultz, M.D., University of British Columbia; Daniel Wolff, M.D., University of Regensburg

**Members:** Hildegard Greinix, M.D., University of Graz; Sophie Paczesny, M.D., University of South Carolina; Bruce Blazar, M.D., University of Minnesota; Stefanie Sarantopoulos, M.D., Ph.D., Duke University; Joseph Pidala, M.D., Ph.D., Moffitt Cancer Center; Corey Cutler, M.D., M.P.H., FRCPC, Dana Farber Cancer Institute; Gerard Socie, M,D., Ph.D., St-Louis Hospital, Paris; Paul Martin, M.D., Fred Hutchinson Cancer Research Center; Meredith Cowden, M.A., LPCC-S, Cowden Foundation.

**PROJECT MANAGEMENT GROUP**

Julia Lam, NCI; Dariele Marshall, NCI; Romi Sawhney, NCI and Filip Pirsl, NCI.

**ETIOLOGY AND PREVENTION WORKING GROUP 1**

**Co-Chairs**: Stefanie Sarantopoulos, M.D., Ph.D., Duke University and Gerard Socie, M.D., Ph.D., St-Louis Hospital.

**Members:** Mukta Arora, M.D., M.S., University of Minnesota; Iskra Pusic, M.D., Washington University School of Medicine; Yoshi (Yoshihiro) Inamoto, M.D., National Cancer Institute-Japan; Leo (Leonido) Luznik, M.D., Johns Hopkins University; Pavan Reddy, M.D., University of Michigan; Jerome Ritz, M.D., Dana-Farber Cancer Institute; Betty Hamilton, M.D., Cleveland Clinic; Kirsten Williams, M.D., Emory School of Medicine; Annie Im, M.D., University of Pittsburgh Medical College ; John Koreth, M.D., Ph.D., Dana-Farber Cancer Institute; Paul Carpenter, BSc., MBBS., Fred Hutchinson Cancer Research Center; Jacki (Jacqueline)Mays, DDS., MHSc., Ph.D., NIH National Institute of Dental and Craniofacial Research.

**EARLY DIAGNOSIS AND PREEMPTION WORKING GROUP 2**

**Co-Chairs**: Corey Cutler, M.D., MPH, FRCPC, Dana Farber Cancer Institute and Joseph Pidala, M.D., Ph.D, Moffit Cancer Center.

**Members:** Francis Ayuk, M.D., University Medical Center Hamburg; Joseph Pidala, M.D., Ph.D., Moffitt Cancer Center; Helene Schoemans, M.D., University of Leuven; Fiona Dignan BSc, Med Sci, MBChB, FRCP, FRCPath, M.D., Manchester Royal Infirmary; Eric Tykacyk, M.D., Ph.D., FAAD, Vanderbilt University; Mary Flowers, M.D., Fred Hutchinson Cancer Research Center; Shernan Holtan, M.D., University Minnesota; Carrie Kitko, M.D., Vanderbilt University; Nosha Farhadfar, M.D., University of Florida; Geoff Cuvelier, M.D., FRCPC, Cancer Center Manitoba;

Geoffrey Hill, M.D., FRACP, FRCPA, Fred Hutchinson Cancer Research Center; Anita Lawitschka, M.D., Ph.D., Medizinische Universitat Wien.

**Contributors:** John Levine, M.D. Mount Sinai Hospital; Paul Carpenter BSc., MBBS, Fred Hutchinson Cancer Research Center; Joycelyn Palmer. Ph.D., City of Hope; Tim Randolph, Ph.D., Fred Hutchinson Cancer Research Center.

**Ophthalmology:** Sandeep Jain, M.D., University of Illinois**;** Philipp Steven, M.D., University of Cologne; Zhonghui Lou, M.D., Ph.D., Massachusetts General Hospital**;** Yoko Ogawa, M.D., Ph.D., Keio University School of Medicine**;** Michael Stern, Ph.D., Purdue Biological Sciences Committee.

**Pulmonary**: Gregory Yanik, M.D., University of Michigan; Guang-Shing Cheng, M.D., Fred Hutchinson Cancer Research Center.

**Dermatology:** Edward Cowen, M.D., M.H.Sc., National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH

**TREATMENT OF CHRONIC GVHD WORKING GROUP 3**

**Co-Chairs**: Bruce Blazar, M.D., University of Minnesota; Hildegard Greinix, M.D., University of Graz

**Members:** Daniel Couriel, M.D., M.S., University of Utah; Amin Alousi, M.D., MD Anderson Cancer Center; Vijaya Bhatt, M.D., University of Nebraska; Nataliya Buxbaum, National Cancer Institute, Center for Cancer Research; Kelli Macdonald, Ph.D., Berghofer Research Institute; Robert Zeiser, M.D., University Medical Center Freiburg; Jörg P. Halter, M.D., Universitätsspital Basel; Attilio Olivieri, M.D., Universita Politecnica delle Marche; Alex (Aleksandr) Lazaryan, M.D., MPH, Ph.D., Moffitt Cancer Center; Zachariah DeFilip, M.D., Massachusetts General Hospital; Drazen Pulanic, M.D., Ph.D., University of Zagreb; Ted Gooley, Ph.D., Fred Hutchinson Cancer Research Center; Lori Henderson, Ph.D., NCI Program Officer; Donna Prezepiorka, M.D., Ph.D., US Food and Drug Administration; Geoffrey Hill, M.D., FRACP, FRCPA, Fred Hutchinson Cancer Research Center.

**MORBID FORMS OF CHRONIC GVHD WORKING GROUP 4**

**Co-Chairs**: Daniel Wolff, M.D., University of Regensburg; Sophie Paczesny, M.D., University of South Carolina

**Members:** Jamie Todd, M.D., Duke University; Guang-Shing Cheng, M.D., Fred Hutch; Ajay Sheshadri, M.D., M.S., MDACC; Resat Cinar, Pharm., Ph.D., MBA, NIH; Vedran Radojcic, M.D., University of Utah; Robert Lafyatis, M.D., University of Pittsburgh; Bianca Santomasso, M.D., Ph.D., MSKCC; Ervina Bilic, M.D., Ph.D., University of Zagreb;

Sandeep Jain, M.D., University Illinois; Takanori Teshima, M.D., Ph.D., Hokkaido University; Olaf Penack, M.D., Ph.D., Charite Berlin; David Jacobsohn, M.D., ScM, Children's National.

**Contributors:** Guang-Shing Cheng, M.D., Fred Hutchinson Cancer Research Center; Philipp Steven, M.D., University of Cologne, Yoko Ogawa, M.D., Ph.D., Keio University School of Medicine; Donna Przepiorka, M.D., Ph.D., US Food and Drug Administration; Linda M. Griffith, M.D., MHS, Ph.D., NIH, National Institute of Allergy and Infectious Disease; Kelli MacDonald, Ph.D., Berghofer Research Institute; Robert Zeiser, M.D., University Hospital Freiburg; Vijaya Bhatt, M.D., University of Nebraska Medical Center; W. Taylor Kimberly, M.D., Ph.D., Massachusetts General Hospital; Klemens Angstwurm; Geoffrey D. E. Cuvelier, M.D., FRCPC, Cancer Care Manitoba; E. Holler; Edward W. Cowen, M.D., M.H.Sc, NIH, National Institute of Arthritis and Musculoskeletal and Skin Diseases; Kirsten Williams, M.D., Emory University; Anne Bergeron, M.D., Ph.D., St-Louis Hospital; Sarah Anand, M.D., University of Michigan; Shannon R McCurdy, M.D., University of Pennsylvania; Robery Jenq, M.D., MD Anderson Cancer Center; Eneida R. Nemecek, M.D., M.S., MBA, Oregon Health & Science University; Daniel Saban, Ph.D., Duke University; Iago Pinal Fernandez, M.D., Ph.D., NIH, National Institute of Arthritis and Musculoskeletal and Skin Diseases.

**INDUSTRY SUMMIT**

**Co-Chairs:** Corey Cutler, M.D., MPH, FRCPC, Dana Farber Cancer Institute and Daniel Couriel, M.D., M.S., University of Utah.

**ADVOCACY SUMMIT**

**Co-Chairs**: Meredith Cowden, M.A., LPCC-S., Cowden Foundation and Daniel Wolff, M.D., University of Regensburg.

**Members:** Michelle Bishop, Ph.D., University of Florida**;** Guy Bouguet, France Lymphome Espoir**;** Peggy Burkhard, NbmtLink; Chiara DeBiase,M.S., Anthony Nolan ; Christina Ferraro, CNP, Cleveland Clinic; Steven Pavletic, M.D., M.S., NCI; Naomi Pineda, BC Children’s Hospital; Helene Schoemans, M.D., University of Leuven; Katie Schoeppner, MSW, LICSW, National Marrow Donor Program; Kirk Schultz, M.D., University of British Columbia; Susan Stewart, BMT InfoNet.

**ASTCT-NIH-EBMT JOINT CHRONIC GVHD EDUCATION COMMITTEE**

**Co-Chairs**: Steven Pavletic, M.D., M.S., NCI and Navneet Majhail, MBBS, M.D., M.S., Cleveland Clinic.

**Members:** Kirk Schultz, M.D., University of British Columbia; Paul Carpenter, BSc, MBBS, Fred Hutchinson Cancer Research Center**;** Syed Abutalib, M.D, Cancer Treatment Centers of America**;** Olaf Penack, M.D., Swedish Medical Center**;** Kyra Newman, MSW, American Society for Transplantation and Cellular Therapy.

**INTERNATIONAL ASPECTS**

Nada Hamad, BSc, MSc Forensic, MBBS, FRACP, FRCPA, SpeCetClinRes (oncology), BMTSANZ President and Mahmoud Aljurf, M.D., MPH., King Faisal Hospital Riyadh.

**ACKNOWLEDGEMENTS**

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For post-conference comments and questions please email to:

CGVHD2020@mail.nih.gov