

NIH 2014 Chronic GVHD Consensus Project on Criteria for Clinical Trials

Final Agenda

Tuesday, June 17, 2014, 8.00 AM – 6.30 PM
National Cancer Institute at Shady Grove, Room TE406

Chairs: Steven Pavletic, Georgia Vogelsang, Stephanie Lee

Meeting agenda

Morning

7.15 – 8.00 Registration of participants

8.15-8.30 Opening, charge to the panels and welcome
Steven Pavletic, Roy Wu, Lee Helman

8.30-9.45 *I. Diagnosis and Staging WG report*
Mary Flowers, Fred Hutchinson Cancer Research Center, Seattle;
Madan Jagasia, Vanderbilt University, Nashville, Co-Chairs

Commentators: Daniel Wolff and Carrie Kitko

9.50-10.50 *II. Histopathology WG report*
David Kleiner, NIH, Bethesda;
Howard Shulman, University of Washington, Seattle, Co-Chairs

Commentators: Elisabeth Huber and David Myerson

Break (10 min)

11.00-12.15 *III. Biomarkers and Biology WG report*
Kirk Schultz, University of British Columbia, Vancouver, Canada;
Sophie Paczesny, University of Indiana, Indianapolis Co-Chairs

Commentators: Hildegard Greinix (Biomarkers)
John DiPersio and Paul Martin (Biology)

12.15-12.45 External reviewer comments WG I.-III
First reviewer: Gerard Socie; Second reviewer: Joe Antin
WG co-chairs

12.45-1.45 Lunch time

Afternoon

1.45-3.00 *IV. Response Criteria WG report*
Steven Pavletic, NIH, Bethesda
Stephanie Lee, FHCRC, Seattle, Co-Chairs

Commentators: Attilio Olivieri and Francis Ayuk

3.05-4.05 *V. Ancillary and Supportive Care WG report*
Dan Couriel, University of Michigan, Ann Arbor
Paul Carpenter, FHCRC, Seattle, Co-Chairs

Commentators: Joerg Halter, Anita Lavitschka and Kirsten Williams

Break (15 min) – *Group photo opportunity*

4.20-5.35 *VI. Design of Clinical Trials WG report*
Paul Martin, FHCRC, Seattle
Corey Cutler, Harvard University, Boston, Co-Chairs

Commentators: Steven Devine and Rafael Duarte

5.40-5.55 Special commentary: NIH Criteria and clinical practice
(Daniel Wolff, Hildegard Greinix, Anita Lawitschka and Joerg Halter)

6.00-6.30 External reviewer comments WG IV.-VI.
First reviewer: Joe Antin, Second reviewer: Gerard Socie
WG co-chairs

6.30 Adjournment (Pavletic, Lee)

6.45 Busses depart for the group dinner
New Fortune, 16515 Frederick Ave, Gaithersburg, MD 20877

The meeting flow

- This meeting is focused on six working group (WG) presentations of the work since June 2005. Sessions are designed to allow ample time for the discussion.
- All six WG documents posted on the 2014 website are drafts and works in progress solely for the purpose of this meeting. A two month public comments period will start after the conference.

Project steering committee members

Mary Flowers, Seattle; Madan Jagasia, Nashville; David Kleiner, Bethesda; Howard Shulman, Seattle; Kirk Schultz, Vancouver; Sophie Paczesny, Indianapolis; Dan Couriel, Ann Arbor; Paul Carpenter, Seattle; Paul Martin, Seattle; Corey Cutler, Boston; Georgia Vogelsang, Baltimore; Stephanie Lee, Seattle; Steven Pavletic, Bethesda

Ex officio members:

Roy Wu, NCI; William Merritt, NCI; Linda Griffith, NIAID, Nancy DiFronzo, NHLBI; Myra Jacobs, nbmtLINK; Sue Stewart, BMTInfoNet, Meredith Cowden, Meredith Cowden GVHD foundation

Project management group

Steven Pavletic, NCI; Mary Custer, NCI; Sawhney, Romi, NCI; Licia Masuch, NCI; Monica Pittenger, NCI; Roy Wu, NCI; William Merritt, NCI; Linda Griffith, NIAID

I. Diagnosis and Staging Working Group

*Mary Flowers, Fred Hutchinson Cancer Research Center, Seattle;
Madan Jagasia, Vanderbilt University, Nashville, Co-Chairs*

Panel Members

Daniel Weisdorf, University of Minnesota, Minneapolis
Yoshi Inamoto, National Cancer Center, Tokyo, Japan
Holly Kerr, University of British Columbia, Vancouver, Canada
Mukta Arora, University of Minnesota, Minneapolis
Sally Arai, Stanford University, Palo Alto
Nathaniel Treister, Harvard University, Boston
David Jacobsohn, DC Children's Hospital, Washington DC
Sandra Mitchell, NCI, Bethesda
Kirsten Williams, DC Children's Hospital, Washington DC
Manuel Datiles, NEI, Bethesda
Edward Cowen, NCI, Bethesda
Theo Heller, NIDDK, Bethesda
Pam Stratton, NICHD, Bethesda
Roy Wu, NCI, Bethesda
Hildegard Greinix, Vienna University, Austria
Rafael Duarte, University of Barcelona, Spain
Alfonso Vigorito, University of Campinas, Brazil
Jeanne Palmer, Mayo Clinic, Scottsdale, AZ

II. Histopathology Working Group

*David Kleiner, NIH, Bethesda;
Howard Shulman, Fred Hutchinson Cancer Research Center,
Seattle, Co-Chairs*

Panel Members

Nathaniel Treister, Harvard University, Boston
Tom Morton, University of Washington, Seattle
Sangeeta Hingorani, University of Washington, Seattle
Diana Cardona, Duke University, Durham
Kay Washington, Vanderbilt University, Nashville
Joel Greenson, University of Michigan, Ann Arbor
Thomas Horn, Harvard University, Boston
Thomas Longerich, University of Heidelberg, Germany
Andreas Kreft, University of Mainz, Germany
Elisabeth Huber, University of Regensburg, Germany
Victor Prieto, M.D. Anderson Cancer Center, Houston, TX

III. Biomarkers and Biology Working Group

Kirk Schultz, University of British Columbia, Vancouver, Canada;
Sophie Paczesny, University of Indiana, Indianapolis Co-Chairs

Panel Members

Bruce Blazar, University of Minnesota, Minneapolis
Marcel Van den Brink, MSKCC, New York
Stefanie Sarantopoulos, Duke University, Durham
Robertson Parkman, Stanford University, Palo Alto
Jerome Ritz, Harvard University, Boston
John Hansen, Fred Hutchinson Cancer Research Center, Seattle
David Miklos, Stanford University, Palo Alto
Joseph Pidala, Moffitt Cancer Center, Tampa
Kenneth Cooke, Johns Hopkins University, Baltimore
John Barrett, NHLBI, Bethesda
Linda Griffith, NIAID, Bethesda
Fran Hakim, NCI, Bethesda
Ron Gress, NCI, Bethesda
Daniel Fowler, NCI, Bethesda
Leo Luznik, Johns Hopkins University, Baltimore
Marc Walton, FDA, Silver Spring
Maria Chan, FDA, Silver Spring
Julia Lathrop, FDA, Silver Spring
Russek-Cohen Estelle, FDA, Silver Spring

Biology task force leaders:

Kenneth Cooke, David Miklos, Jerome Ritz, Bruce Blazar

IV. Response Criteria Working Group

Steven Pavletic, NIH, Bethesda
Stephanie Lee, FHCRC, Seattle, Co-Chairs

Panel Members

Paul Martin, FHCRC, Seattle
Yoshi Inamoto, FHCRC, Seattle
Madan Jagasia, Vanderbilt University, Nashville
Marcie Hall, FHCRC, Seattle
Joseph Pidala, Moffitt Cancer Center, Tampa
Carrie Kitko, University of Michigan, Ann Arbor
Iskra Pusic, Washington University, St. Louis
John Koreth, Harvard University, Boston
David Jacobsohn, DC Children's, Washington DC
Sandra Mitchell, NCI, Bethesda
Donna Przepiorka, FDA, Silver Spring
Dignan Fiona, University of Manchester, UK
Anita Lavitschka, University of Vienna, Austria

Daniel Wolff, University of Regensburg, Germany
Andrea Bacigalupo, University of Genoa, Italy
Attilio Olivieri, University delle Marche, Ancona, Italy

V. Ancillary and Supportive Care Working Group

Dan Couriel, University of Michigan, Ann Arbor
Paul Carpenter, FHCRC, Seattle, Co-Chairs

Panel Members

Bipin Savani, Vanderbilt University, Nashville
Carrie Kitko, University of Michigan, Ann Arbor
Laura Johnston, Stanford University, Palo Alto
Joerg Halter, University of Basel, Switzerland
Anita Lavitschka, University of Vienna

VI. Design of Clinical Trials Working Group

Paul Martin, FHCRC, Seattle
Corey Cutler, Harvard University, Boston, Co-Chairs

Panel Members

John Koreth, Harvard University, Boston
Marcie Hall, FHCRC, Seattle
Holly Kerr, University of British Columbia, Vancouver
Paul Carpenter, FHCRC, Seattle
Irwin Walker, McMaster University, Hamilton
Mary Horowitz, CIBMTR, Milwaukee
Brent Logan, CIBMTR, Milwaukee
Gorgun Akpek, MDACC, Phoenix
Jacqueline Mays, NIDCR, Bethesda
William Merritt NCI, Bethesda
Donna Przepiorka FDA, Silver Spring
Mohamad Mohty, Saint-Antoine Hospital, Paris

Additional Contributors to the Working Groups:

George McDonald, FHCRC, Seattle (Diagnosis and Staging, Response Criteria)
Guang-Shing Cheng, FHCRC, Seattle (Diagnosis and Staging)
Avi Rosenberg, NCI, NIH, Bethesda (Histopathology)
Mirjana Ziemer, University Leipzig, Germany (Histopathology)
David Myerson, FHCRC, Seattle (Histopathology)
Mark Schubert, FHCRC, Seattle (Diagnosis and Staging, Response Criteria)
Carol Bassim, NIDCR, NIH, Bethesda (Response Criteria)
Tina Dietrich-Ntoukas, University of Regensburg, Germany (Diagnosis and Staging)
Janine Clayton, NEI, NIH, Bethesda (Diagnosis and Staging, Response Criteria)
Gerhardt Hildebrandt, University of Utah, Salt Lake City (Response Criteria)
Karen Syrjala, FHCRC, Seattle (Ancillary and Supportive Care)
Anthony Opiari, University of Michigan, Ann Arbor (Ancillary and Supportive Care)
Sean Smith, University of Michigan, Ann Arbor (Ancillary and Supportive Care)
Flora Hoodin, University of Michigan, Ann Arbor (Ancillary and Supportive Care)
Juan Gea-Banacloche, NCI, NIH, Bethesda (Ancillary and Supportive Care)
Robert Knobler, University of Vienna (Diagnosis and Staging)
Sharon Elad, University of Rochester, New York (Response Criteria, Ancillary Support Care)

List of Some Organizations Represented

National Cancer Institute

NIH, Office of Rare Diseases Research

National Institute of Allergy and Infectious Disease

National Heart Lung and Blood Institute

The Health Resources and Services Administration, Division of Transplantation

Chronic GVHD Consortium, supported by ORDR and NCI

American Society for Blood and Marrow Transplantation

Center for International Bone and Marrow Transplant Research

Canadian Blood and Marrow Transplant Group

European Group for Blood and Marrow Transplantation

German-Austrian-Swiss chronic GVHD study group

Brazilian Chronic GVHD Consortium

Pediatric Blood and Marrow Transplant Consortium

South American transplant centers

Patient and research advocacy groups

- Meredith Cowden GVHD foundation

- National bmtLINK

- BMTInfoNet

- National Marrow Donor Program

Pharmaceutical industry

US Food and Drug Administration

Major US transplant centers

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