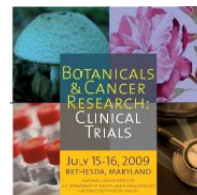


Botanicals and Cancer Research: Clinical Trials Workshop Agenda

Natcher Conference Center
National Institutes of Health
July 15-16, 2009



WEDNESDAY, JULY 15, 2009

7:30 – 8:30 AM

Registration and Refreshments- Atrium

8:30 – 1:45 PM

WELCOME & PLENARY SESSIONS - Balcony B

8:30 – 9:00 AM

Welcome

Jeffrey D. White, M.D., Office of Cancer Complementary and Alternative Medicine (OCCAM)/National Cancer Institute (NCI)

9:00 – 9:30 AM

Plenary Session 1

Targets, Pathways, and Networks in Pre-Clinical Models

Emma Shtivelman, Ph.D., Bionovo, Inc.
James McMahon, Ph.D., Center for Cancer Research (CCR)/NCI

9:30 – 10:00 AM

Plenary Session 2

Botanical Drug Product Issues

Ikhlas Khan, Ph.D., University of Mississippi

10:00 – 10:25 AM

BREAK – Atrium

10:25 – 10:55 AM

Plenary Session 3

Clinical Trial Design and Implementation I

Debu Tripathy, M.D., University of Texas Southwestern Medical Center
Francis Law, Ph.D., Simon Fraser University

10:55 – 11:25 AM

Plenary Session 4

Clinical Trial Design and Implementation II

Ed Chu, M.D., Yale University Cancer Center

11:25 – 11:55 AM

Plenary Session 5

Role of Industry in Botanical Drug Development

Freddie Ann Hoffman, M.D., Heterogeneity, LLC

12:00 – 1:00 PM

LUNCH – Atrium

NCI's Natural Products Collection Programs: Lessons Learned

Dave Newman, D.Phil., Natural Products Branch/NCI

1:00 – 1:30 PM

Plenary Session 6

Obtaining Grant Funding for Botanical Drug Research

Isis Mikhail, M.D., Dr.P.H., M.P.H., OCCAM/NCI

Barbara Sorkin, Ph.D., National Center for Complementary and Alternative Medicine (NCCAM)

1:30 – 1:45 PM

Charge to Working Groups

Jeffrey D. White, M.D., OCCAM/NCI

1:45 – 5:00 PM

WORKING GROUPS – Introduction of Group Participants
See rooms listed below

1:45 – 2:30 PM

Group I: Targets, Pathways, and Networks in Pre-Clinical Models

Room: C1/C2

Co-Chairs: Emma Shtivelman, Ph.D., Bionovo, Inc.

James McMahon, Ph.D., CCR/NCI

Group II: Botanical Drug Product Issues

Room: H

Co-Chairs: Ikhlas Khan, Ph.D., University of Mississippi

Trevor Castor, Ph.D., Aphios

Group III: Clinical Trial Design and Implementation I

Room: D

Co-Chairs: Debu Tripathy, M.D., University of Texas Southwestern Medical Center

Francis Law, Ph.D., Simon Fraser University

Group IV: Clinical Trial Design and Implementation II

Room: F1/F2

Co-Chairs: Ed Chu, M.D., Yale University Cancer Center

Tommy Cheng, Ph.D., Yale University Medical Center

Group V: Role of Industry in Botanical Drug Development

Room: G1

Co-Chairs: Freddie Ann Hoffman, M.D., Heterogeneity, LLC

Shaw Chen, Ph.D., Food and Drug Administration (FDA)

Group VI: Obtaining Grant Funding for Botanical Drug Research

Room: G2

Co-Chairs: Isis Mikhail, M.D., Dr.P.H., M.P.H., OCCAM/NCI

Barbara Sorkin, Ph.D., NCCAM

2:30 – 2:55 PM

BREAK – Atrium

2:55 – 5:00 PM

Continue in Working Group Sessions

5:00 – 6:00 PM

ADJOURN to Reception - Natcher Atrium

THURSDAY, JULY 16, 2009
Natcher Conference Center

7:30 – 8:30 AM **Registration and Refreshments- Lower Level**

8:30 – 8:35 AM **Welcome – Room: E1/E2**
Jeffrey D. White, M.D., OCCAM/NCI

8:35 – 8:45 AM **Go to Working Group Sessions**

8:45 – 10:30 AM **WORKING GROUPS – Questions and Discussion**
See rooms listed below

Group I: Targets, Pathways, and Networks in Pre-Clinical Models **Room: C1/C2**
Co-Chairs: Emma Shtivelman, Ph.D., Bionovo, Inc.
James McMahon, Ph.D., CCR/NCI

Group II: Botanical Drug Product Issues **Room: H**
Co-Chairs: Ikhlas Khan, Ph.D., University of Mississippi
Trevor Castor, Ph.D., Aphios

Group III: Clinical Trial Design and Implementation I **Room: B**
Co-Chairs: Debu Tripathy, M.D, University of Texas Southwestern Medical Center
Francis Law, Ph.D., Simon Fraser University

Group IV: Clinical Trial Design and Implementation II **Room: F1/F2**
Co-Chairs: Ed Chu, M.D., Yale University Cancer Center
Tommy Cheng, Ph.D., Yale University Medical Center

Group V: Role of Industry in Botanical Drug Development **Room: G1**
Co-Chairs: Freddie Ann Hoffman, M.D., Heterogeneity, LLC
Shaw Chen, Ph.D., FDA

Group VI: Obtaining Grant Funding for Botanical Drug Research **Room: G2**
Co-Chairs: Isis Mikhail, M.D., Dr.P.H., M.P.H., OCCAM/NCI
Barbara Sorkin, Ph.D., NCCAM

10:30 – 10:45 AM **BREAK - Lower Level**

10:45 AM – 12:15 PM **Working Groups Report Back – Room: E1/E2**

10:45 – 12:00 PM **Working Groups Report Back – Room: E1/E2**

10:45 AM – 11:30 PM **Group I: Targets, Pathways, and Networks in Pre-Clinical Models**
Co-Chairs: Emma Shtivelman, Ph.D., Bionovo, Inc.
James McMahon, Ph.D., CCR/NCI

- Presentation (15 minutes)

- Discussion (30 minutes)

11:30 AM – 12:15 PM

Group II: Botanical Drug Product Issues

Co-Chairs: Ikhlas Khan, Ph.D., University of Mississippi
Trevor Castor, Ph.D., Aphios

- Presentation (15 minutes)
- Discussion (30 minutes)

12:15 – 1:15 PM

LUNCH (on your own)

1:15 – 4:45 PM

Working Groups Report Back (Cont.) – Room: E1/E2

1:15 – 2:30 PM

Group III & IV: Clinical Trial Design and Implementation I and II

Co-Chairs: Debu Tripathy, M.D., University of Texas Southwestern Medical Center

Francis Law, Ph.D., Simon Fraser University

Ed Chu, M.D., Yale University Cancer Center

Tommy Cheng, Ph.D., Yale University Medical Center

- Presentation (30 minutes)
- Discussion (45 minutes)

2:30 – 3:15 PM

Group V: Role of Industry in Botanical Drug Development

Co-Chairs: Freddie Ann Hoffman, M.D., Heterogeneity, LLC

Shaw Chen, Ph.D., FDA

- Presentation (15 minutes)
- Discussion (30 minutes)

3:15 – 3:30 PM

BREAK - Lower Level

3:30 – 4:15 PM

Group VI: Obtaining Grant Funding for Botanical Drug Research

Co-Chairs: Isis Mikhail, M.D., Dr.P.H., M.P.H., OCCAM/NCI

Barbara Sorkin, Ph.D., NCCAM

- Presentation (15 minutes)
- Discussion (30 minutes)

4:15 – 4:45 PM

Final Opportunity for Comments

4:45 – 5:00 PM

Closing Remarks: The Future of Botanicals Research

Jeffrey D. White, M.D., OCCAM/NCI