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 Shitivelman, 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 – 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)
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| 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 |