AGENDA

NCI Workshop on Criteria for Use of Omics-Based Predictors in Clinical Trials

THURSDAY, JUNE 23

7:30-8:00  REGISTRATION & CONTINENTAL BREAKFAST

8:00-8:15  WELCOME & OPENING REMARKS

   Barbara A Conley, MD

8:15-8:30  NCI PERSPECTIVE & OVERVIEW OF GOALS

   Lisa M McShane, PhD

8:30-9:10  KEYNOTE ADDRESS

   James H Doroshow, MD

9:10 -9:30 WHEN IS A PREDICTOR CLINICALLY USEFUL?

   Michael J Birrer, MD PhD

9:30-10:30 PANEL DISCUSSION: CHALLENGES IN SPECIMEN QUALITY AND HANDLING

   Organizer & Moderator: David Eberhard, MD PhD

   Panelists:

   Sunil Badve, MD

   Stephen M Hewitt, MD PhD

   Andrea L Richardson, MD PhD

   Reena Philip, PhD

10:30-10:45 COFFEE BREAK

10:45-11:45 PANEL DISCUSSION: ASSAY CHALLENGES, PITFALLS, AND SOLUTIONS

   Organizer & Moderator: Mickey Williams, PhD and William L Bigbee, PhD

   Panelists:

   Daniel Chan, PhD

   Patrick Hurban, PhD
Charles M Perou, PhD
Donna Roscoe, PhD
Leming Shi, PhD

11:45-12:45   LUNCH

12:45-1:05   SAMPLE REUSE IN LARGE SCALE GENE EXPRESSION STUDIES
            Paul T Spellman, PhD

1:05-1:25   OVERVIEW OF MODEL BUILDING STRATEGIES AND PERFORMANCE ASSESSMENT METHODS
            Jeremy M G Taylor, PhD

1:25-1:40   ASSESSING ANALYTIC REPRODUCIBILITY OF PREDICTIONS
            Kevin K Dobbin, PhD

1:40-2:00   BLINDED CLINICAL VALIDATIONS - ROLE OF HONEST BROKER
            Michael LeBlanc, PhD

2:00-3:00   PANEL DISCUSSION: DOCUMENTATION, ROBUSTNESS, AND REPRODUCIBILITY OF COMPUTATIONAL MODELS, INCLUDING THE APPROPRIATE SOURCE DATA
            Organizer & Moderator: Jill P Mesirov, PhD
            Panelists:
            Keith Baggerly, PhD
            Robert L Becker, MD
            Roger Peng, PhD
            Paul T Spellman, PhD
            Pablo Tamayo, PhD

3:00-3:20   CLINICAL TRIAL DESIGNS FOR EVALUATING OMICS-BASED PREDICTORS
            Richard M Simon, DSc

3:20-3:45   REGULATORY REQUIREMENTS
            Robert L Becker, MD
            Lisa D White, PhD
3:45-4:00  COFFEE BREAK

4:00-5:30  BREAKOUT GROUPS

A. Specimen Issues

B. Assay Issues

C. Model Development, Specification, and Retrospective Performance Evaluation

D. Prospective Phase II and Phase III Clinical Trial Design and Data Stewardship in Clinical Trials

E. Regulatory and Legal Issues

FRIDAY, JUNE 24

7:30-8:00  CONTINENTAL BREAKFAST

8:00-11:35  PRESENTATIONS BY BREAKOUT GROUPS

(25 min. presentation of recommendations +15 min. floor discussion for each group)

8:00-8:40  BREAKOUT GROUP A

8:40-9:20  BREAKOUT GROUP B

9:20-10:00  BREAKOUT GROUP C

10:00-10:15  COFFEE BREAK

10:15-10:55  BREAKOUT GROUP D

10:55-11:35  BREAKOUT GROUP E

11:35-12:00  GENERAL FLOOR DISCUSSION AND WRAP-UP