

FDA-AACR Workshop

To Test or Not To Test – That Is The Question: DPD Deficiency And Weighing Potential Harms

Bethesda Marriott Pooks Hill

January 16 | 9:00 AM – 3:00 PM ET

Workshop Co-Chairs

Jennifer Gao, MD, U.S. Food and Drug Administration

Patricia LoRusso, DO, PhD (hc), FAACR, Yale Cancer Center

AGENDA

9:00 AM INTRODUCTION

9:00 AM **Welcome & Introduction**
Richard Pazdur, MD, U.S. Food and Drug Administration

9:05 AM **Workshop Overview**
Patricia LoRusso, DO, PhD (hc), FAACR, Yale Cancer Center

9:10 AM FIRESIDE CHAT

- Paul Kluetz, MD, U.S. Food and Drug Administration
- Michael Pacanowski, PharmD, MPH, U.S. Food and Drug Administration
- Karen Merritt, Advocates for Universal DPD/DPYD Testing
- Ravin Garg, MD, Maryland Oncology Hematology

9:40 AM BREAK

9:55 AM SESSION 1: CURRENT LANDSCAPE – DPD DEFICIENCY TESTS AND FDA PRODUCT LABELING

9:55 AM **Moderator Introduction**
Michael Pacanowski, PharmD, MPH, U.S. Food and Drug Administration

10:00 AM **The Importance of Dihydropyrimidine Dehydrogenase in 5-FU Treatment**
Robert Diasio, MD, Mayo Clinic

10:05 AM **AMP's Recommendations for Clinical DPYD Genotyping Allele Selection**
Victoria Pratt, PhD, Agena Bioscience

10:10 AM **Fluoropyrimidine and DPD Deficiency: A Regulatory History of FDA Labeling**
Evan Bryson, PharmD, BCOP, U.S. Food and Drug Administration

10:20 AM PANEL DISCUSSION

Additional Panelists

- Sam Abdelghany, PharmD, MHA, BCOP, Smilow Cancer Hospital at Yale New Haven
- D. Max Smith, PharmD, BCPS, MedStar Health & Georgetown University
- Jill Bates, PharmD, MS, BCOP, CPT, FASHP, Department of Veterans Affairs

11:05 AM BREAK

11:15 AM SESSION 2: CURRENT LANDSCAPE – CLINICAL CONSIDERATIONS AND EVIDENCE

11:15 AM Moderator Introduction

Jennifer Gao, MD, U.S. Food and Drug Administration

11:20 AM When Should a Tumor Biomarker be Applied in the Clinic?

Daniel Hayes, MD, FACP, FASCO, The University of Michigan

11:25 AM Clinical Utility of Pre-treatment for *DPYD* Testing

Daniel Hertz, PharmD, PhD, The University of Michigan College of Pharmacy

11:30 AM Guidelines and Diagnostics: Details Matter

Alan Venook, MD, FASCO, The University of California, San Francisco

11:35 AM PANEL DISCUSSION

Additional Panelists

- **Asal Sayas**, Former White House Office of Science and Technology Policy
- **Jill Bates, PharmD, MS, BCOP, CPT, FASHP**, Department of Veterans Affairs
- **Ravin Garg, MD**, Maryland Oncology Hematology

12:30 PM LUNCH BREAK (ON YOUR OWN)

1:30 PM SESSION 3: FUTURE DIRECTION – WHERE DO WE GO FROM HERE?

1:30 PM Moderator Introduction

William Pierce, PharmD, MPH, BCPS, U.S. Food and Drug Administration

1:35 PM Current State of *DPYD* Genotype Testing at Mayo Clinic

Christina Wu, M.B., B.Ch., MD, Mayo Clinic at Arizona

1:40 PM PANEL DISCUSSION

Additional Panelists

- **Robert Schuck, PharmD**, U.S. Food and Drug Administration
- **Patricia LoRusso, DO, PhD (hc), FAACR**, Yale Cancer Center
- **Karen Merritt**, Advocates for Universal DPD/DPYD Testing
- **Alan Venook, MD**, The University of California, San Francisco
- **Victoria Pratt, PhD**, Agena Bioscience

2:40 PM PATIENT PERSPECTIVE

2:40PM Asal Sayas, Former White House Office of Science and Technology Policy

2:50 PM CLOSING REMARKS

2:50 PM Paul Kluetz, MD, U.S. Food and Drug Administration

2:55 PM Patricia LoRusso, DO, PhD (hc), FAACR, Yale Cancer Center