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