THE FORUM
For Collaborative Research℠

Panel Discussion

Berkeley Public Health

Moderated Panel Discussion

Moderator:

Melissa Palmer, Chief Medical Officer, Gannex Pharma (a wholly owned company of Ascletis Pharma)

Panelists:

Mark Avigan, Associate Director, Office of Surveillance Epidemiology, U.S. Food and Drug Administration
Michelle Berrey, President of Research & Development and Chief Medical Officer, Intercept Pharmaceuticals
Elizabeth Brunt, Emeritus Professor, Pathology and Immunology, Washington University School of Medicine in St. Louis
Zachary Goodman, Director of Hepatic Pathology Consultation and Research, Inova Fairfax Hospital
Cynthia Guy, Professor of Pathology, Professor of Medicine, Duke University School of Medicine
Prakash Jha, Medical Officer, Division of Molecular Genetics and Pathology Office of Product Evaluation and Quality, CDRH/ U.S. Food and Drug Administration
David Kleiner, Senior Research Physician, National Cancer Institute, NIH
Ruby Mehta, Medical Officer, Division of Hepatology and Nutrition, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Arie Regev, Head, Safety Advisory Hub, Eli Lilly & Company
Arun Sanyal, VCA

Panel Discussion Questions

- How many pathologists should evaluate screening and EOS histologic slides in a NASH clinical trial?
- Should EOS histology be evaluated as soon as possible or is it sufficient to wait until all patients or a predetermined number of patients have completed the trial?
- What/how many members should make up an external DILI monitoring committee/ when to set up/ blinded/ unblinded members prior to study start – Who should be on the committee? – pathologist /clinical development/ statistician/ DILI expert?