Moderated Panel Discussion

Moderator:
- Veronica Miller, Forum for Collaborative Research

Panelists:
- Manal Abdelmalek, Duke University
- Andrew Beck, PathAI
- Pierre Bedossa, Institute of Translational Research, Newcastle University
- Weijie Chen, U.S. Food and Drug Administration, CDRH
- Samer Gawrieh, Indiana University
- Prakash Jha, U.S. Food and Drug Administration, CDRH
- David Kleiner, NIH National Cancer Institute
- Mathieu Petitjean, Pharmanest
- Vlad Ratziu, Hôpital Pitié Salpêtrière
- Massimo Siciliano, Università Cattolica del Sacro Cuore / external AIFA / EMA consultant
- Dean Tai, HistolIndex
Panel Discussion Questions (1 / 2)

- How is digital pathology/ AI currently being used in NASH clinical trials?
- What are the strengths of digital pathology / AI for NASH trials?
- What are the limitations of digital pathology / AI for NASH trials?
- What are the logistic issues that need to be considered?
  - How can they be addressed?
- Are there histopathology standards and best practices that could be adopted in NASH clinical trials that could improve digital assessment?
- What can be learned from other therapeutic areas? (i.e., oncology)
Panel Discussion Questions (2 / 2)

- What regulatory guidance exist regarding the use of digital pathology/ AI in clinical trials?
  - Are they, or could they, be applied to NASH trials?
  - Are there areas not addressed where regulatory questions remain?
- How can digital pathology/ AI help to generate evidence for clinical trials?
  - To support the development of non-invasive biomarkers?
- Could digital pathology be positioned as part of the current histology endpoint?
  - Should this be general, or should it vary depending on the different mechanism of actions?
- What is the practicality of translation of digital pathology as a biomarker from clinical research to clinical practice?