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**, HistoIndex

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?

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