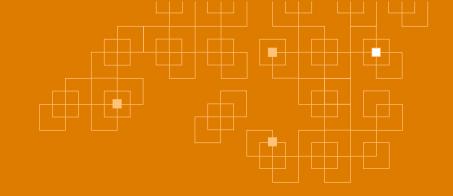


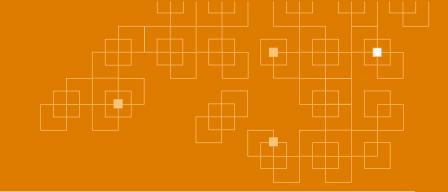


HBV Forum Co-Chair Introductory Remarks





2023 Publications



REVIEW

HDV RNA Assays: Performance characteristics, clinical utility and challenges

Wedemeyer, Heiner^{1,2,3,4}; Leus, Mitchell⁵; Battersby, Thomas R.⁶; Glenn, Jeffrey⁷; Gordien, Emmanuel⁸; Kamili, Saleem⁹; Kapoor, Hema¹⁰; Kessler, Harald H.¹¹; Lenz, Oliver¹²; Lütgehetmann, Marc^{13,14}; Mixson-Hayden, Tonya⁹; Simon, Christian O.¹⁵; Thomson, Michael¹⁶; Westman, Gabriel^{17,18}; Miller, Veronica⁵; Terrault, Norah¹⁹; Lampertico, Pietro^{20,21}; On behalf of the HDV RNA Assays Writing Group at the HBV Forum

Author Information ⊗

Hepatology ():10.1097/HEP.000000000000584, August 28, 2023. | DOI: 10.1097/HEP.00000000000584



Clinical Infectious Diseases

VIEWPOINTS







Chronic Hepatitis B Finite Treatment: Similar and Different Concerns With New Drug Classes

Marion G. Peters,^{1,®} Man-Fung Yuen,² Norah Terrault,³ John Fry,⁴ Pietro Lampertico,^{5,6} Ed Gane,⁷ Carey Hwang,⁸ Luisa M. Stamm,⁹ Mitchell Leus,¹⁰ Mala K. Maini,¹¹ Patricia Mendez,¹² Isabelle Lonjon-Domanec,¹³ Thomas Berg,¹⁴ Su Wang,¹⁵ Poonam Mishra,¹⁶ Eric Donaldson,¹⁶ Stephanie Buchholz,¹⁷ Veronica Miller,¹⁰ and Oliver Lenz;¹⁸ on behalf of the HBV Forum Stopping Finite Therapy Working Group

Ongoing Working Groups



- MAPPED* Working Group (co-leads: Jordan Feld and Michael Biermer)
 - Aim: to understand relationship between HBV patient heterogeneity and drug mechanisms of action, assessing the
 assumptions made in clinical development programs, how assumptions evolve overtime based on results
 - Activity: manuscript conceptualization in progress
- HDV Co-Infection Working Group (co-leads: Heiner Wedemeyer and Norah Terrault)
 - Aim: to facilitate HDV diagnostic and therapeutic development through discussions on standardization of HDV RNA
 assays, efficacy endpoint definitions, and other aspects of HDV drug development and regulatory science
 - Activity: continued discussion on HDV RNA assay development challenges following paper recently published in Hepatology

* MAPPED = Mechanisms of Action and Patient Populations: Emphasizing Diversity

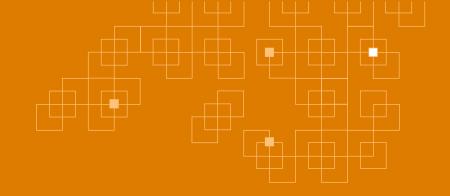


Ongoing Working Groups



- Biomarkers Database Working Group (co-leads: Markus Cornberg and Doug Mayers)
 - Aim: to assess range of diversity (demographic, clinical, biomarkers) among patients in trials of novel therapeutic
 and combination regimens for CHB, assembling database of HBV trial information to facilitate collective learning
 - Activity: landscaping literature review of HBV trials and discussions with stakeholders on clinical data sharing
- Checkpoint Inhibitors Working Group (co-leads: Adam Gehring and Sue Currie)
 - Aim: to advance the regulatory path for checkpoint inhibitors (PD-1/PD-L1) in CHB patients by identifying major safety and efficacy concerns and assessing key learnings from oncology, where these therapies were first approved
 - Activity: continued working group discussions in planning for assembling a database on checkpoint inhibitor trials





Thank You!