

# Session 2: HDV Co-Infection Working Group

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# HDV Co-Infection Working Group



- Launch of this working group at the previous HBV Forum 8 meeting in June 2022
  - Very enthusiastic support for HBV Forum to tackle HDV issues
  - Three broad areas were initially considered:
    - 1) Screening and testing
    - 2) Diagnostics
    - 3) Treatment endpoints
- We will first focus on diagnostics, namely HDV RNA assays
  - This will lead to future discussions on screening, endpoints, therapies, etc.
  - Thank you to Pietro Lampertico for conceptualizing this paper

# HDV Assays Writing Group



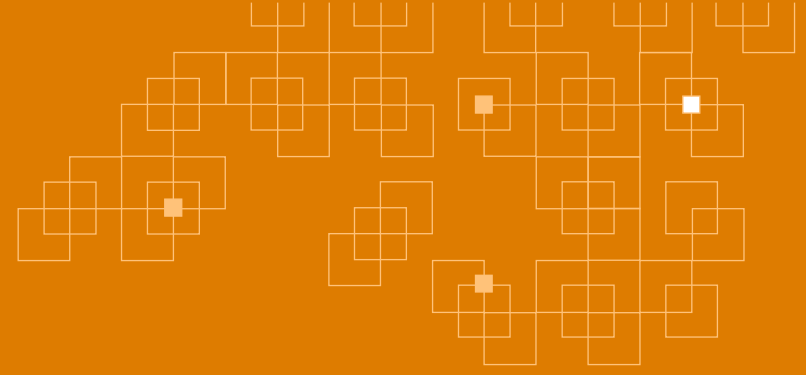
- Writing group will produce a manuscript on technical aspects of HDV RNA assays and limitations in the field
  - Perspectives from clinicians, virologists, industry, and regulators

# Writing Group Membership



- Clinicians, virologists, industry, and regulators

Veronica Miller	Jeffrey Glenn	Thomas Battersby
Norah Terrault	Gavin Cloherty	Maria Ines Garcia
Heiner Wedemeyer	Oliver Lenz	Michael Thomson
Pietro Lampertico	Christian Simon	Gabriel Westman
Marc Lütgehetmann	Jackie Reeves	
Emmanuel Gordien	Hema Kapoor	
Harald Kessler	Tonya Hayden	



# HDV Assays Draft Paper Outline

# 1) General overview on HDV



## 2) Current diagnostic landscape in HDV and HDV-RNA assays: review of literature

- Could make mention here on diagnostic algorithms: HDV Ab testing and reflex testing to HDV RNA?

# 3) Role of HDV RNA in diagnosis and monitoring untreated patients



- 3a) Definition of response
  - What aspects of HDV RNA assays are needed for determining current endpoints?



## 4) HDV-RNA assays: challenges from the virological point of view

- 4a) Molecular epidemiology of HDV
  - Poverty of sequence data is a major challenge on the industry side for developing HDV RNA assays
  - Important to characterize HDV genetic diversity

# 5) HDV-RNA assays currently available: pros and cons (Clinical and technical)



## 6) Future studies/perspectives

- Some thoughts:
  - HDV RNA in the blood – what is clinically significant?
  - HDV RNA in the tissue vs. in the blood
- What other considerations?

# 7) Recommendations



- Clarity on “undetectable HDV RNA” – how do we define undetectable?
- Assay standardization and validation

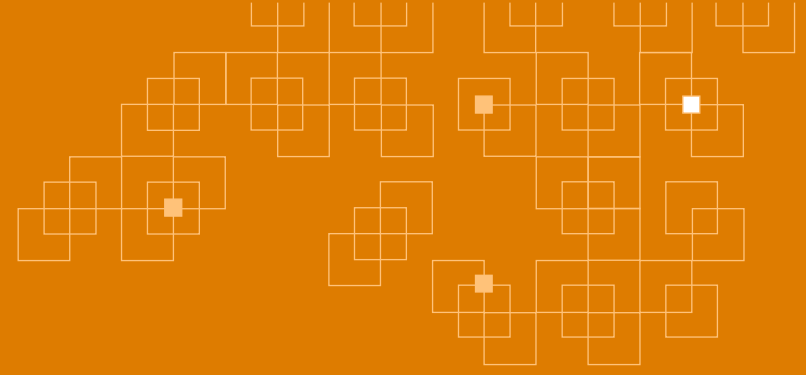
# 8) Conclusions



# Audience Q&A: Paper Outline



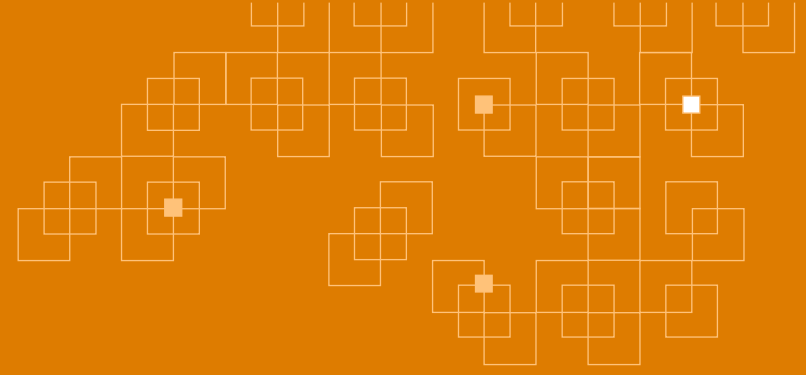
- 1) General overview on HDV
- 2) Current diagnostic landscape in HDV and HDV-RNA assays currently available: review of the literature
- 3) Role of HDV RNA in diagnosis and monitoring untreated patients
  - 3a) Definition of response
- 4) HDV-RNA assays: challenges from the virological point of view
  - 4a) Molecular epidemiology of HDV
- 5) HDV-RNA assays currently available: pros and cons (Clinical and technical)
- 6) Future studies/perspectives
- 7) Recommendations
- 8) Conclusions



# Regulatory Perspective on HDV Diagnostics

**Maria Ines Garcia, *FDA CDRH***

**Michael Thomson, *FDA CDER***



# Audience Q&A