

Current Status of RLSE vs VSE

Work to Date

- Focus on early disease, F2/F3 patients
- Forum Working Group on NITs for a New RLSE
- Presentation by Seema Desai, *“Update on Forum RLSE Project”*

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Updated Focus

- Shifting focus to later stage disease, F3/F4 patients
- Presentation by Michelle Long, *“Early Clinical Progression Endpoints Manuscript”*
- Presentation by Laurent Castera, *“Baveno 8 Update on Risk Stratification of Cirrhosis”*

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Updated Focus

- “Use of NITs to identify progression to cirrhosis could also be considered for development as a VSE. The FDA strongly encourages ongoing work to characterize NIT thresholds that can identify progression to cirrhosis with high sensitivity and specificity to provide sufficient evidence to support this context of use as a VSE.”

Anania FA, Hager R, Higgins K, Makar GA, Siegel J, Tran TT. Non-invasive tests: Establishing efficacy for metabolic dysfunction-associated steatohepatitis beyond the biopsy-Current perspectives from the Division of Hepatology and Nutrition, US Food and Drug Administration. Hepatology. 2026.

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Future for the Forum

- Convening multiple webinars, workshops with Liver Forum members
- Goals of building consensus through collaboration, moving towards a VSE with progression to cirrhosis