



Discussion Topics

1. RSV Vaccine Safety in Pediatric Populations

- 1.1 Please discuss whether the currently available evidence indicates a potential safety concern more broadly applicable to the evaluation of RSV vaccine candidates in infants and toddlers. Please discuss the applicability to:
 - a. different vaccine technologies (e.g., live-attenuated RSV, viral-vectored, mRNA, and subunit protein vaccines); and
 - b. different antigenic conformations (e.g., stabilized preF or other RSV protein prototypes).
- 1.2 Based on the currently available evidence, please discuss current nonclinical and clinical safeguards, and recommend whether any additional nonclinical and clinical information should be considered and/or precautions taken when evaluating RSV vaccine candidates in infants and toddlers.



Discussion Topics

2. Sequential Administration of RSV Monoclonal Antibodies (mAbs) followed by RSV Vaccines in Infants and Toddlers

- 2.1 Please discuss whether currently available evidence suggests potential RSV mAb (e.g., nirsevimab) - RSV vaccine interactions that may affect active immunization in infants and toddlers.
- 2.2 Based on currently available evidence, please discuss and recommend whether any additional factors and data should be considered when evaluating RSV mAb - RSV vaccine interactions, including potential impact of administration of RSV mAbs on safety and/or effectiveness of subsequent parenteral or mucosal administration of RSV vaccines.



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