



## Issues for Panel Discussion

- Discuss COVID-19 related MAVs as a clinically meaningful endpoint
- Discuss the criteria for defining COVID-19 related MAVs
- Discuss the pros and cons of having an adjudication committee
- Discuss any additional concerns or recommendations regarding the use of MAVs as a component of the primary endpoint for trials in participants with mild-to-moderate COVID-19



# Please Comment on COVID-19 Related MAVs as a Clinically Meaningful Endpoint



# Please Comment on the Proposed Criteria for Classifying a MAV as COVID-19 Related

- A worsening of one or more COVID-19 signs or symptoms such that it is at least moderate severity and interferes with the participant's daily activities
- A persistent COVID-19 sign or symptom that is severe and interferes with the participant's daily activities
- A complication of COVID-19 (e.g., a thrombotic event)\*
- An exacerbation of underlying conditions due to COVID-19\*

\*Specific criteria to be defined

# Please Comment on the Pros and Cons of Having an Adjudication Committee



## Pros

- Improves overall consistency and accuracy in MAV assessment:
  - Assessment of worsening/persistence of COVID-19 signs and symptoms and linkage of these signs/symptoms to an MAV
  - Assessment of COVID-19 complications and exacerbations of underlying conditions
  - Capturing interventions from an MAV

## Cons

- The feasibility of obtaining necessary source documentation
- COVID-19 can affect any body system and there are no specific, well-defined supporting laboratory, imaging, or physical evidence that must be present (other than a positive SARS-CoV-2 test)
- May not be necessary given that the inclusion of COVID-19 related MAVs in the primary endpoint is only intended for double-blind, randomized, controlled trials



Please comment on any additional concerns or recommendations regarding the use of MAVs as a component of the primary endpoint for trials in participants with mild-to-moderate COVID-19

