

Discussion Items

1. Please discuss FDA's approach to safety and effectiveness data as outlined in the respective guidance documents.
2. Please discuss considerations for continuation of blinded Phase 3 clinical trials if an EUA has been issued for an investigational COVID-19 vaccine.
3. Please discuss studies following licensure and/or issuance of an EUA for COVID-19 vaccines to:
 - a. Further evaluate safety, effectiveness and immune markers of protection
 - b. Evaluate the safety and effectiveness in specific populations