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