

Discussion Topics



1. Controlled Human Infection Model—*Disease Endpoint*

- a. Do *B. pertussis* controlled human infection models, in their current stage of development, produce signs and symptoms of disease that accurately and reliably reflect human disease caused by natural infection with *B. pertussis*?
- b. If yes, are *B. pertussis* controlled human infection models, in their current stage of development, sufficiently robust models of natural infection and disease to provide the primary human data to support effectiveness of new pertussis vaccines for booster vaccination of adults?

2. Controlled Human Infection Model—*Colonization Endpoint*

- a. Can prevention of *B. pertussis* colonization be considered a surrogate endpoint that is reasonably likely to predict clinical benefit, specifically prevention of pertussis disease?
- b. If yes, do *B. pertussis* controlled human infection models of colonization, in their current stage of development, accurately and reliably reflect colonization following natural *B. pertussis* exposure?