

QUESTIONS FOR THE COMMITTEE

1. Please comment on Nabi's *post hoc* inclusion and exclusion criteria for the classification of subjects as successes or failures following HBIG administration in the setting of OLT.
2. Given the observational nature of the information provided, the data limitations (including a priori definitions), and the lack of analysis plan, is inference about the outcomes of Nabi/s HBIG administration in this setting appropriate?
3. Do the submitted data from retrospective chart reviews, an uncontrolled PK assessment and an open label access program demonstrate efficacy of Hepatitis B Immune Globulin (H) (HBIG) (Nabi-HB™) for the OLT HBV immunoprophylaxis indication?