

## **Design Issues in Future Studies**

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The Division of Antiviral Products (DAVP) has regulatory authority over the development of drugs and therapeutic biologic products for treatment of viral infections, including chronic hepatitis B virus (HBV) infection. Sponsors of new therapies consult DAVP on the design of their clinical trials intended to support approval and marketing of those therapies in the U.S. Design of phase 3 registration trials for HBV therapies is complicated and fraught with challenges related to endpoint selection, duration of therapy, use and selection of active controls, and definitions of treatment response. The presentation will provide background information on the criteria necessary to support product approval, available mechanisms for product approval, DAVP's assessment of the current clinical trial milieu for anti-HBV therapies, and a review of the advice being conveyed to sponsors on the design of proposed phase 3 studies.