



# Data Collection in HABP/VABP Trials: Regulatory Perspective

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Optimizing Operational Efficiencies for Data Collection in HABP/VABP Trials

# Background

- There are several ongoing efforts to streamline antibacterial drug development
- The Agency is aware of challenges with HABP/VABP trials and understands the difficulties in conducting these trials
- Work done through this public-private partnership would be valuable to improve operational efficiencies in HABP/VABP trials

# HABP/VABP Trials

- Public discussions and evaluations of data have helped bring new ideas that should improve feasibility in scientifically informative trials
  - Single HABP/VABP trial with supportive evidence
  - Use of Gram stain as part of the enrollment criteria and ITT as the primary analysis population; sensitivity analysis in the microbiological ITT population
  - Allow 24 hours of prior antibacterial therapy; sensitivity analysis
  - Risk difference acceptable if control mortality rates are low; use of odds ratio for primary analysis not required
  - Consideration for approved active comparators not labeled for HABP/VABP
- Several of these concepts will be included in the revised draft guidance



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# Guidance for Industry Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations

## ***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Lori Bickel at 301-796-0210, or (CBER) Office of Communication, Outreach, and Development at 301-827-1800.

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# Extent of Safety Data Collection

- Guidance provides general advice on simplifying data collection
  - maintain a balance between eliminating data collection that will not be useful and
  - collecting sufficient data to allow adequate characterization of a drug's safety profile given the potential benefits
- Amount and types of safety data collected based on
  - Preclinical findings
  - Disease
  - Patient population
  - Prior experience with the drug/drug class
  - Phase of development
  - Study design

## **Safety Data Collection in HABP/VABP Trials: Considerations**

- If HABP/VABP isn't the first indication being studied, dose and duration is the same as other indications, it should be possible to limit the amount of data collection
- Safety profile reasonably well described, target organs of toxicity identified, data on all laboratory tests need not be collected
- Laboratory tests such as ABG, electrolytes-multiple values/day not informative

## **Safety Data Collection in HABP/VABP Trials: Considerations**

- Lesser frequency of data collection for vital signs in ICU patients may be an option
- Collecting data on all concomitant medications e.g. sedatives /analgesics may not be very informative
- However if there is potential for drug interactions/additive toxicity it may be useful to collect such information
- Important to collect information regarding concomitant use of other antibacterials with overlapping spectrum of activity, especially in noninferiority trials