A Collaboration to Facilitate the Development of Antibacterial Agents for Unmet Need: Streamlining Clinical Trial Protocols

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ABSTRACT

Objective: This multidisciplinary effort aims to identify challenges in clinical trial conduct of antibacterial agents for the treatment of hospital-acquired bloodstream infections (HABP/VABP), and propose alternate approaches to design more efficient trials.

Method: A working group consisting of multidisciplinary partners from academia, industry, patient groups, and government, including the FDA/CDER's Antibacterial Drug Development Task Force, was formed. The working group identified and focused on critical protocol elements whose efficiencies leading to high-quality data could be improved. The Working Group submitted proposals to the FDA/CDER's Antibacterial Drug Development Task Force, which individually or collectively could be introduced to the protocols of clinical trials. The protocol elements prioritized by the working group included study design and endpoints, data collection, and expedited reporting of safety data collection.

RESULTS

Together with a wider group of experts, the working group has identified several key topics for which it is seeking consensus solutions and operational efficiencies leading to high-quality data.

CONCLUSIONS

This endeavor involves a multi-stakeholder team and uses a QbD approach that has explored issues from a multi-angle view. Future work may serve to transform the way HABP/VABP trials are designed and conducted in the future.