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

INTRODUCTION

There are an estimated 548,000 patients with 721,800 healthcare-associated infections (HAIs) in the U.S. Caucasian hospitals based on a survey conducted in 2011. Hospital-acquired pneumonia was reported to be the most common HA (21.6%) per the survey.

Increasing resistance among etiological pathogens of hospital-acquired and ventilator-associated bacterial pneumonia (HAP/VAP) has compounded the problem, underscoring the urgent need for new therapies to treat these infections.

However, HAP/VAP trials are complex; they are typically conducted globally, are operationally difficult, take a long time to enroll, and are therefore expensive and challenging to conduct.

Varying regulatory standards for these global trials have further increased their complexity.

Therefore, innovative approaches are needed to address this important issue.

The goal of this project is to develop alternate approaches for designing HAP/VAP trials that preserve their scientific integrity while increasing their operational efficiency, so as to maximize the information gained for the investment made.

METHODS

The CTTI ABDD HAP/VAP Working Group was convened to include key stakeholders whose remit was to:

1. Enrollment Criteria,
2. Key Design Elements,
3. Data Collection,
4. Safety Considerations

This endeavor involves a multi-stakeholder team and uses a QbD approach that has explored issues and uses a QbD approach that has explored issues and uses a QbD approach that has explored issues and uses a QbD approach that has explored issues and uses a QbD approach that has explored issues and uses a QbD approach that has explored issues and uses a QbD approach that has explored issues and uses a QbD approach that has explored issues.

RESULTS

Together with a wide group of experts, the working group has identified several key topics for which it is seeking consensus solutions.

A global network of about 30 sites with proficiency and interest in HAP/VAP trials and accessibility to the HAP/VAP patient population is under development.

CONCLUSIONS

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