

CTTI Antibacterial Drug Development Program Update

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Antibacterial Drug Development Workstreams

HABP/VABP Pilot study	Identify barriers and seek solutions for the successful conduct of studies	Recommendations on alternate study design elements to overcome barriers	A trial using the recommendations will show that an innovative approach will work, leading to availability of more ABD products
ID Site Networks	Build a pilot network of sites to conduct HABP/VABP studies	Identifying 30-50 sites with proficiency, interest, and accessibility to the patient population for HABP/VABP trials	Streamlining and accelerating the conduct of HABP/VABP studies
HABP/VABP Patient Focus Group	Assess patients risk, tolerance, and willingness to be treated with drugs approved through non-traditional trials, and to participate in the same	Report/manuscript on patients risk /tolerance. Recommendation on public education of new approaches to drug development and associated risk.	Increasing public awareness about the benefits/risk of new approaches to drug development
Data Collection Simplification	Simplify and reduce the amount of (safety) data collected in HABP/VABP studies	Recommendations on critical data to be collected for a shorter CRF design	Accelerating study conduct, and reducing cost associated with excess data collection