CTTI HABP/VABP Pilot Study Planning Meeting

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Clinical trials in crisis

The changing structure of industry-sponsored clinical research: pioneering data sharing and transparency.

Kuntz RE.
Addressing This Need

To identify and promote practices that will increase the quality and efficiency of clinical trials

Public-Private Partnership involving all stakeholders
60+ members
Collaboration Towards Solutions

Clinical investigators/Site Coordinators

Government and regulatory agencies

Industry: pharma bio device CRO

IRBs

Patients / Patient advocacy groups

Academia

Industry trade / Professional organizations

Better Streamlined
Fit for purpose
Clinical Trials
## Portfolio of CTTI Projects

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Better, Streamlined, Fit for Purpose Clinical Trials

Target problem areas in clinical trials
Identify solutions
Formulate recommendations
Gather evidence
Build consensus
Change
CTTI Program: Antibacterial Drug Development (ABDD)

Background:

- Prevalence of antibacterial resistance continues to rise
- Pressing need for drug development in this area
- Resistant infections are a burden to society with serious consequences of morbidity and mortality and healthcare costs
- In 2012, FDA established a task force and engaged CTTI and other organizations to tackle this issue on several fronts
ABDD participants

- CTTI members/all stakeholders
- FDA antibacterial taskforce
- EMA
- FNIH
ABDD Program and Projects

Program

- Antibacterial Drug Development (ABDD)
- Unmet Need in multi resistant bacterial infections
- Hospital Acquired and Ventilator Associated Bacterial Pneumonia (HABP/VABP)
- Pediatric trials

Projects

- Expert Meetings and Think Tanks
- Patient focus groups
- Protocol elements
- Data collection
- Site Networks
- Design Challenges & Barriers
- Parent/Caregiver Perceptions

Design Challenges & Barriers

- Parent/Caregiver Perceptions
Demonstrating HABP/VABP Pilot study

- Streamlining data collection recommendations
- Protocol elements recommendations
- Add’l input from stakeholders
- Site Networks
Objective of Pilot Study

Pilot study Objective:

- Conduct a study that will lead to improved HABP/VABP clinical trial feasibility

Today’s Objective:

- Determine the study design for the CTTI HABP/VABP pilot study
Thank you

Thank you for participating!

The discussion today will be audio-recorded so that we can accurately capture the meeting themes.

No statements or opinions expressed during the meeting today will be specifically attributed to you.

All CTTI meetings encourage open dialogue and discussion.
Interactive Discussion/Microphones

Please Do:

- **Use microphone** when speaking, identify yourself and organization
- **Press the Center Button once and release** to activate your microphone. When the button glows red, begin speaking
- Speak 6-8 inches from the microphone at a conversational volume
- **Turn microphone off**: when you have finished speaking, press button once
- For recognition to speak, please **stand tent card on end**
- If needed: Ask for help from Audio/Visual technician at the rear of the room

Please Don’t:

- **Hold down the button**, this will reset your device
- **Leave microphone on when done speaking**, only 3 microphones work simultaneously
- **Press the button for recognition to speak**, the moderator will recognize individuals for questions whose tent cards are standing on end