Clinical trials in crisis
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

Better Streamlined
Fit for purpose
Clinical Trials

Government and regulatory agencies

Clinical investigators/Site Coordinators

Patients / Patient advocacy groups

Industry: pharma bio device CRO

Academia

IRBs

Industry trade / Professional organizations
## Portfolio of CTTI Projects

<table>
<thead>
<tr>
<th></th>
<th>Investigational plan</th>
<th>Study start-up</th>
<th>Study conduct</th>
<th>Analysis and dissemination</th>
<th>Specialty areas</th>
</tr>
</thead>
</table>
| **Completed projects** | • Large simple trials  
• Uses of electronic data | • Central IRB  
• Site metrics | • Adverse event reporting  
• IND safety  
• Monitoring | | • Long-term opioid data |
| **Current projects** | • Patient groups and clinical trials  
• Pregnancy testing  
• QbD  
• Trials based on registries  
• Remote Clinical Trials | • Central IRB advancement  
• GCP training  
• Informed consent  
• Investigator turnover  
• Recruitment and retention | • Safety case studies  
• IND safety advancement | • State of clinical trials  
• DMCs | • Streamlining HABP/VABP trials  
• Pediatric Antibiotic trials  
• Unmet need in Antibiotic development  
• **HABP/VABP pilot study** |
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 Program and Projects

Program

Antibacterial Drug Development (ABDD)

Projects

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

Design Challenges & Barriers

- Expert Meetings and Think Tanks
- Patient focus groups
- Protocol elements
- Data collection
- Site Networks
- Parent/Caregiver Perceptions
Demonstration 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 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

For recognition to speak, please stand tent card on end.