

# CTTI HABP/VABP Pilot Study

## Planning Meeting

*February 24, 2015*

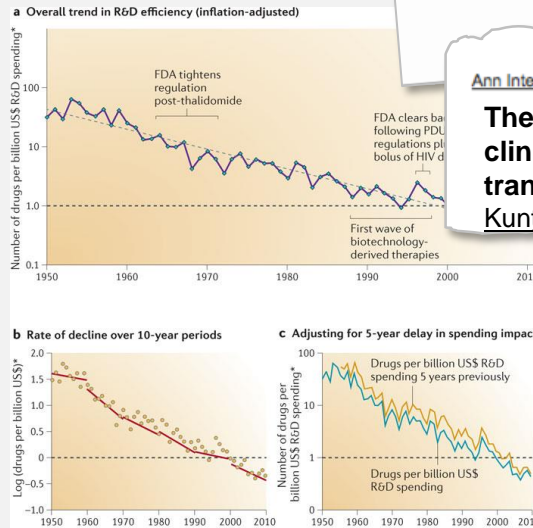
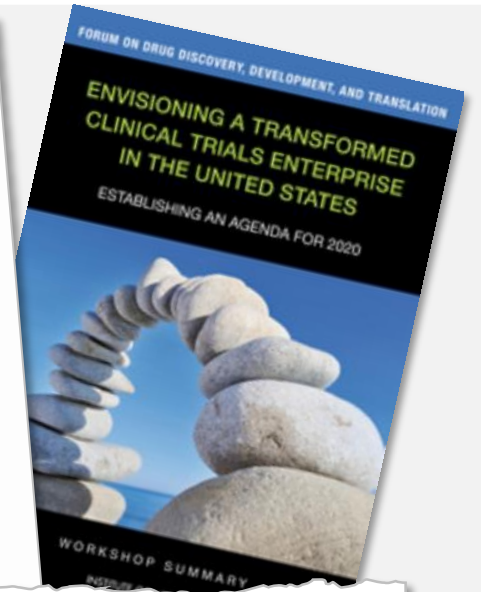
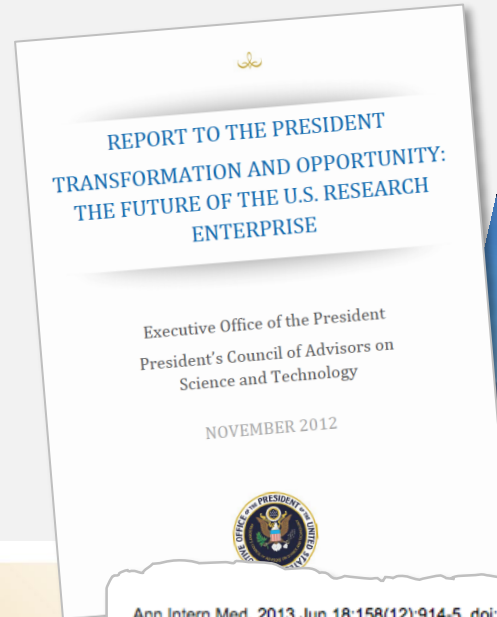
*Pamela Tenaerts, MD, MBA*

*Executive Director, CTTI*



CLINICAL  
TRIALS  
**TRANSFORMATION**  
INITIATIVE

# Clinical trials in crisis



*Ann Intern Med*, 2013 Jun 18;158(12):914-5. doi: 10.7326/0003-4819-158-12-201306180-00011.

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

Kuntz, R

**BROOKINGS**

RESEARCH ▾

EVENTS

EXPERTS

ABOUT ▾

MAR 5

PAST EVENT

**Biomedical Innovation: Identifying Challenges and Prioritizing Needs**

# 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



# Portfolio of CTTI Projects

	Investigational plan	Study start-up	Study conduct	Analysis and dissemination	Specialty areas
Completed projects	<ul style="list-style-type: none"> <li>• Large simple trials</li> <li>• Uses of electronic data</li> </ul>	<ul style="list-style-type: none"> <li>• Central IRB</li> <li>• Site metrics</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse event reporting</li> <li>• IND safety</li> <li>• Monitoring</li> </ul>		<ul style="list-style-type: none"> <li>• Long-term opioid data</li> </ul>
Current projects	<ul style="list-style-type: none"> <li>• Patient groups and clinical trials</li> <li>• Pregnancy testing</li> <li>• QbD</li> <li>• Trials based on registries</li> <li>• Remote Clinical Trials</li> </ul>	<ul style="list-style-type: none"> <li>• Central IRB advancement</li> <li>• GCP training</li> <li>• Informed consent</li> <li>• Investigator turnover</li> <li>• Recruitment and retention</li> </ul>	<ul style="list-style-type: none"> <li>• Safety case studies</li> <li>• IND safety advancement</li> </ul>	<ul style="list-style-type: none"> <li>• State of clinical trials</li> <li>• DMCs</li> </ul>	<ul style="list-style-type: none"> <li>• Streamlining HABP/VABP trials</li> <li>• Pediatric Antibiotic trials</li> <li>• Unmet need in Antibiotic development</li> <li>• <b>HABP/VABP pilot study</b></li> </ul>

# Better, Streamlined, Fit for Purpose Clinical Trials



Formulate recommendations



Change



Build consensus



Identify solutions



Gather evidence



Target problem  
areas in  
clinical trials



# 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

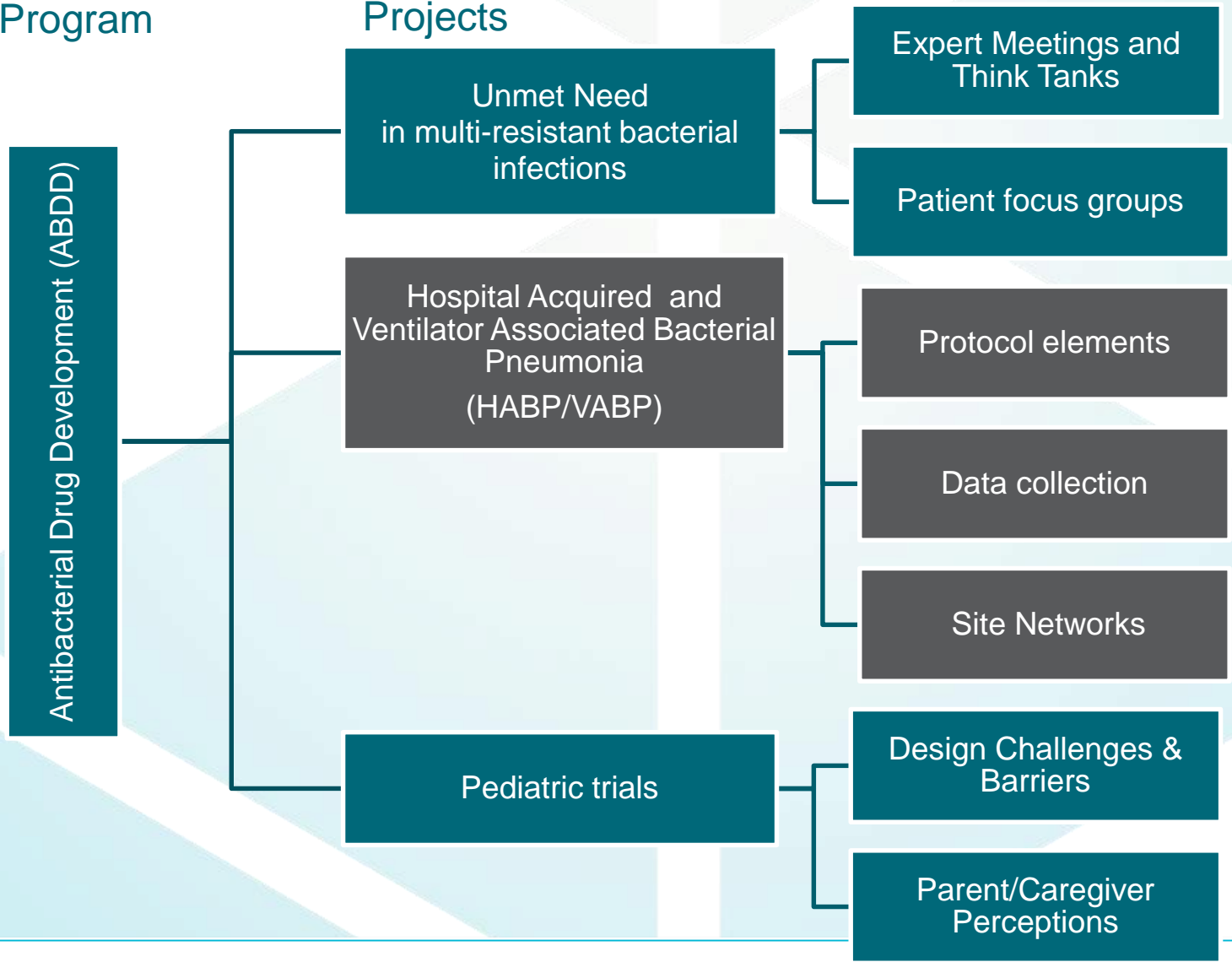
FNIH



# ABDD Program and Projects

Program

Projects



Streamlining data  
collection  
recommendations

protocol elements  
recommendations

Add'l input  
from  
stakeholders

Site Networks

Demonstration  
HABP/VABP  
Pilot study

# 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