CTTI HABP/VABP Pilot Study

Planning Meeting

February 24, 2015

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CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

Clinical trials in crisis

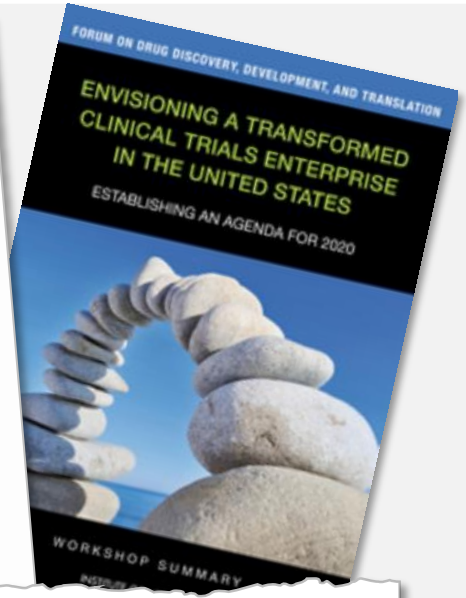
REPORT TO THE PRESIDENT

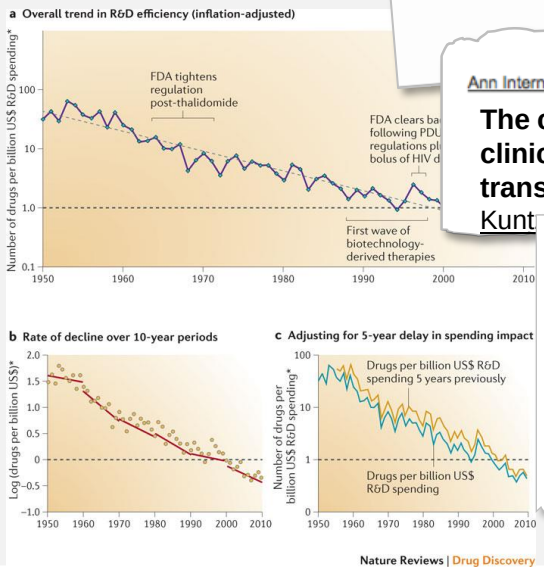
TRANSFORMATION AND OPPORTUNITY: THE FUTURE OF THE U.S. RESEARCH ENTERPRISE

Executive Office of the President

President's Council of Advisors on Science and Technology

NOVEMBER 2012





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.

Kunt

Addressing This Need

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

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

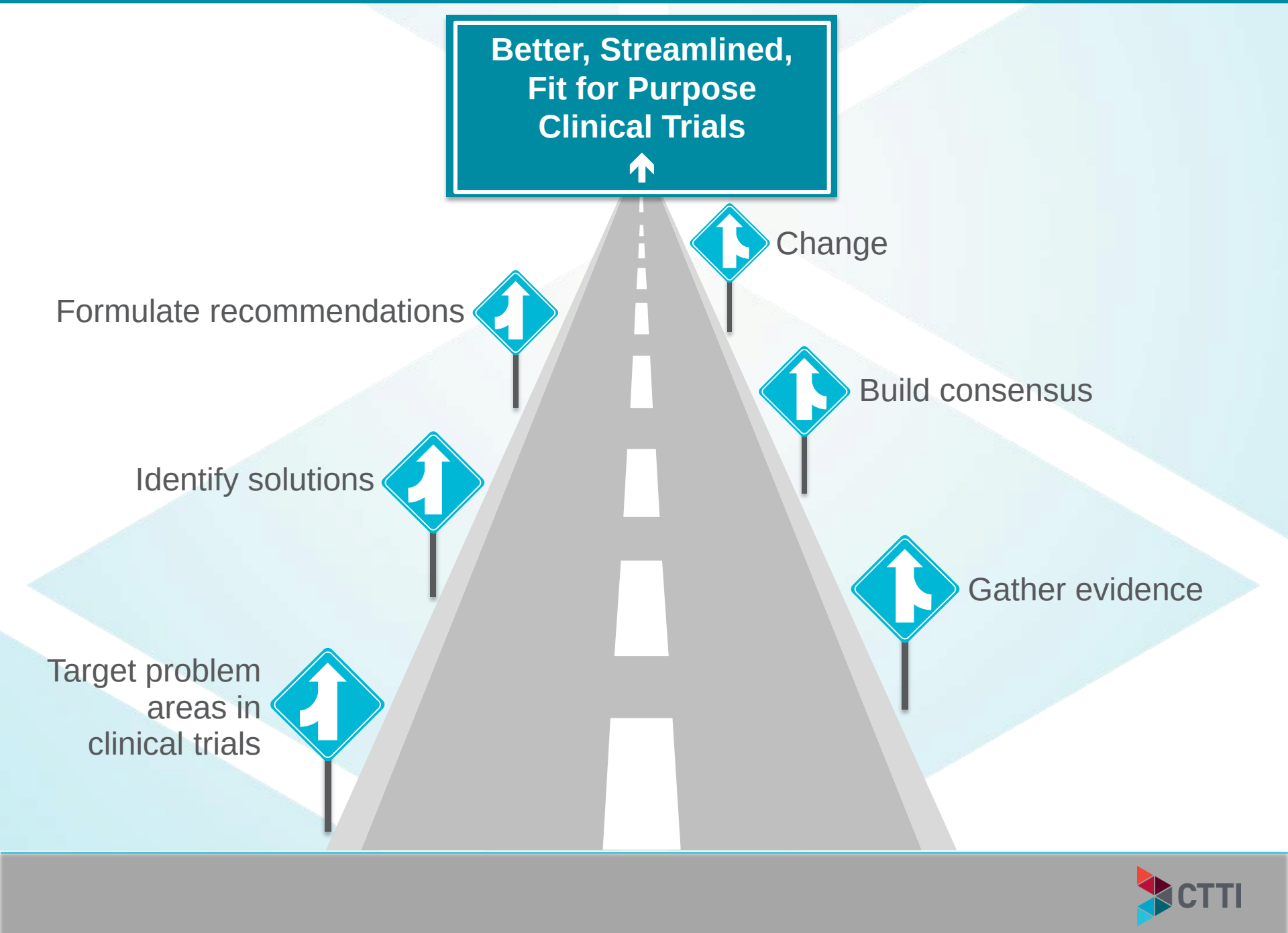
Public-Private Partnership
involving all stakeholders
60+ members

Collaboration Towards Solutions

Portfolio of CTTI Projects

	Investigational plan	Study start up	Study conduct	Analysis and dissemination	Specialty areas
Completed projects	• 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**

CTTI


Better, Streamlined, Fit for Purpose Clinical Trials
Change
Formulate recommendations
Build consensus
Identify solutions
Gather evidence
Target problem areas in clinical trials

CTTI Program: Antibacterial Drug Development (ABDD)

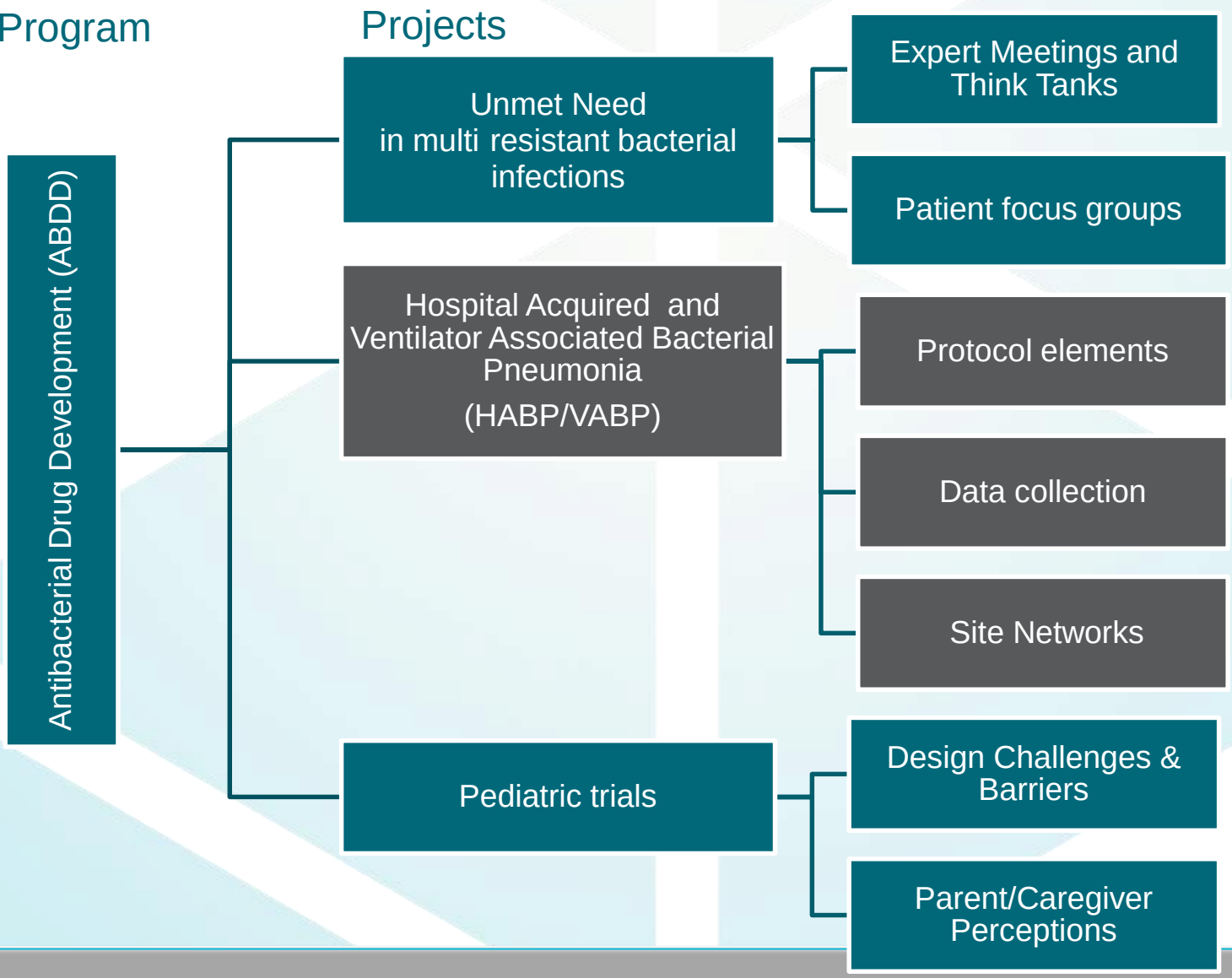
Background:

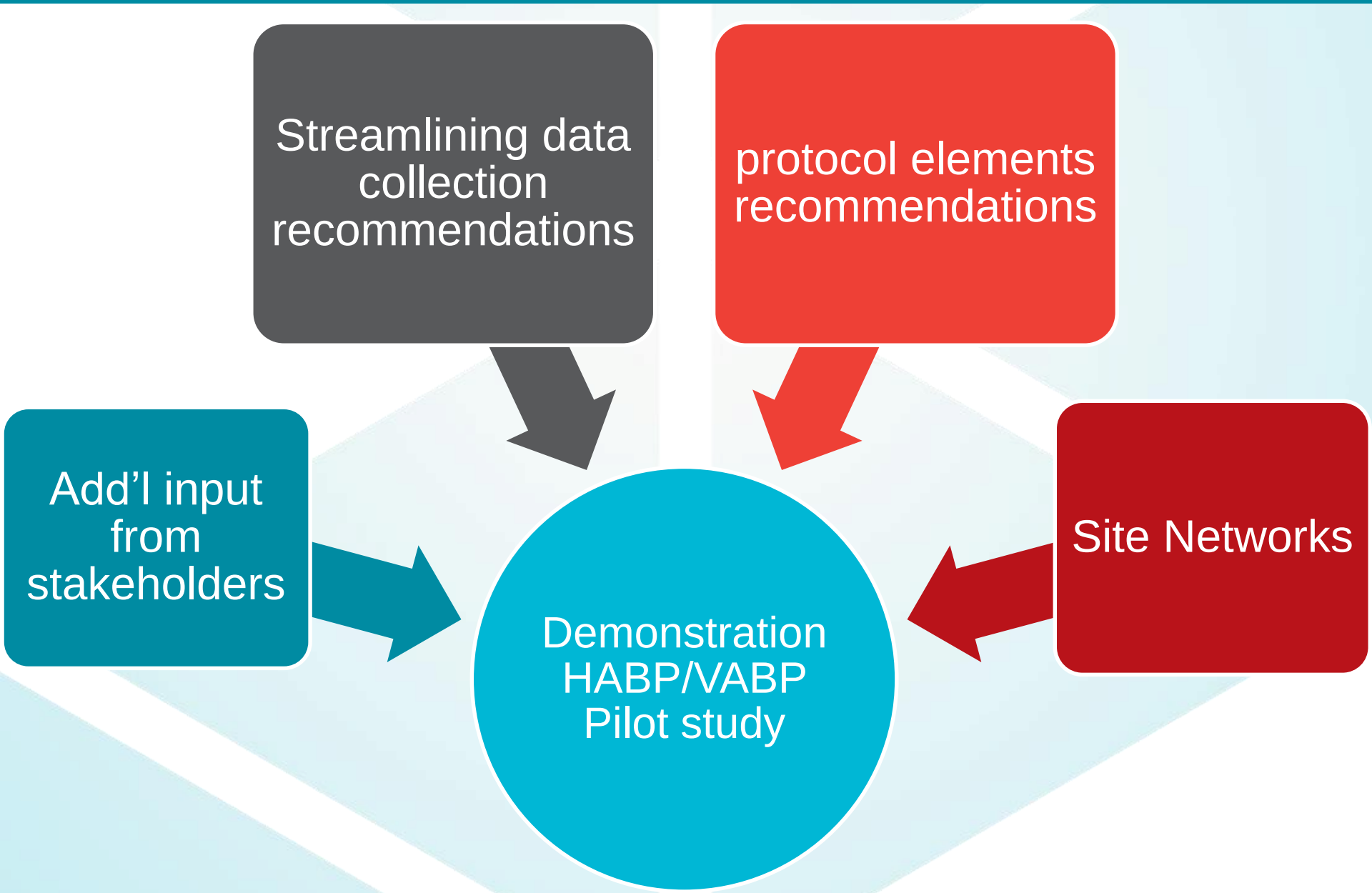
- Prevalence of antibacterial resistance continues to rise
- Pressing need for drug development in this area
- Resistant infections are a burden to society with serious consequences of morbidity and mortality and healthcare costs
- In 2012, FDA established a task force and engaged CTTI and other organizations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

ABDD participants

- CTTI members/all stakeholders
- FDA antibacterial taskforce
- EMA
- FNIH

ABDD Program and Projects




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