CTTI History and Methodology
ABDD Program History

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CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

March 1, 2016

Clinical trials in crisis

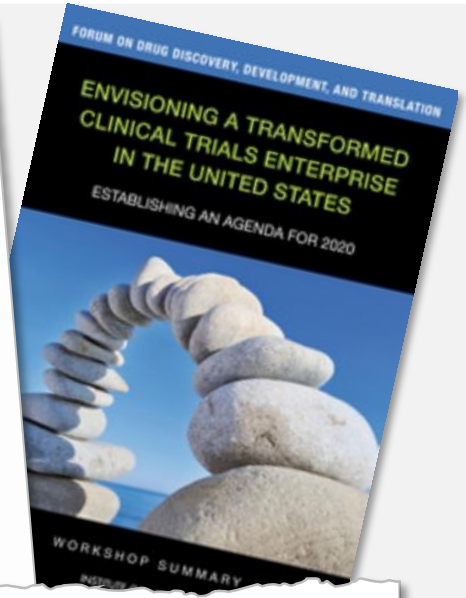
REPORT TO THE PRESIDENT

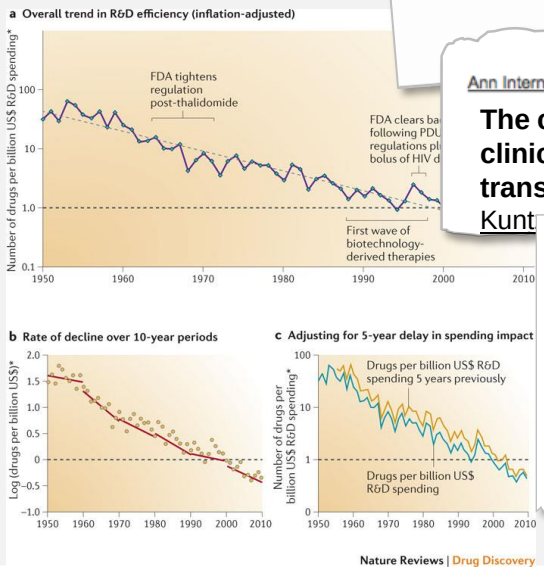
TRANSFORMATION AND OPPORTUNITY: THE FUTURE OF THE U.S. RESEARCH ENTERPRISE

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

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

Public-Private Partnership
Co-Founded by FDA and Duke
involving all stakeholders
70+ members

CTTI Membership

CTTI

How CTTI Works

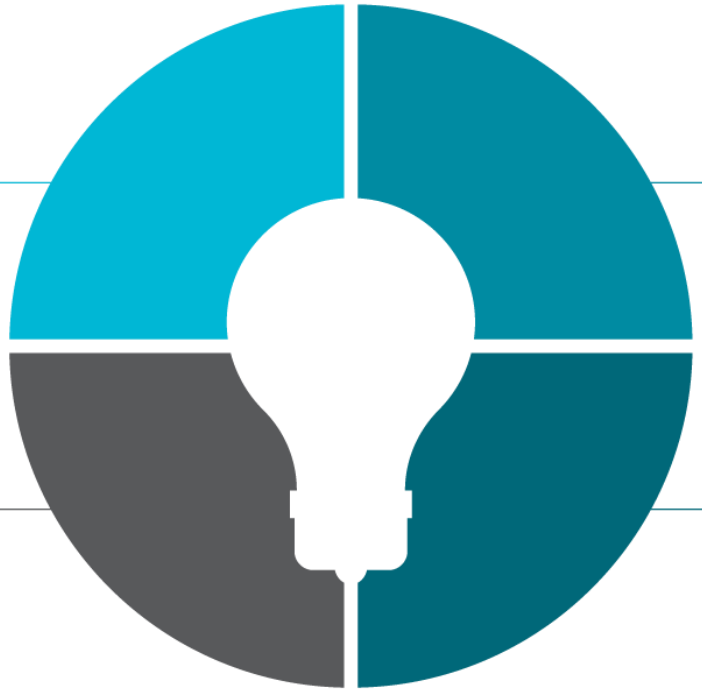
- Engage & value all stakeholders equally
- Understand incentives to maintain non-value added activities and have solutions that are mindful of those incentives
- Plant the seeds for change throughout all phases of a project
- Develop actionable, evidence-based, consensus driven recommendations
- Create and share knowledge, tools & resources to facilitate change that improves clinical trials

CTTI Recommendations

- CTTI projects focus on streamlining and accelerating clinical trials, while ensuring the highest standards of quality and human subjects protection. We provide **actionable**, **evidence-based**, **consensus-driven** recommendations designed to:

Accelerate study start-up times & streamline protocols

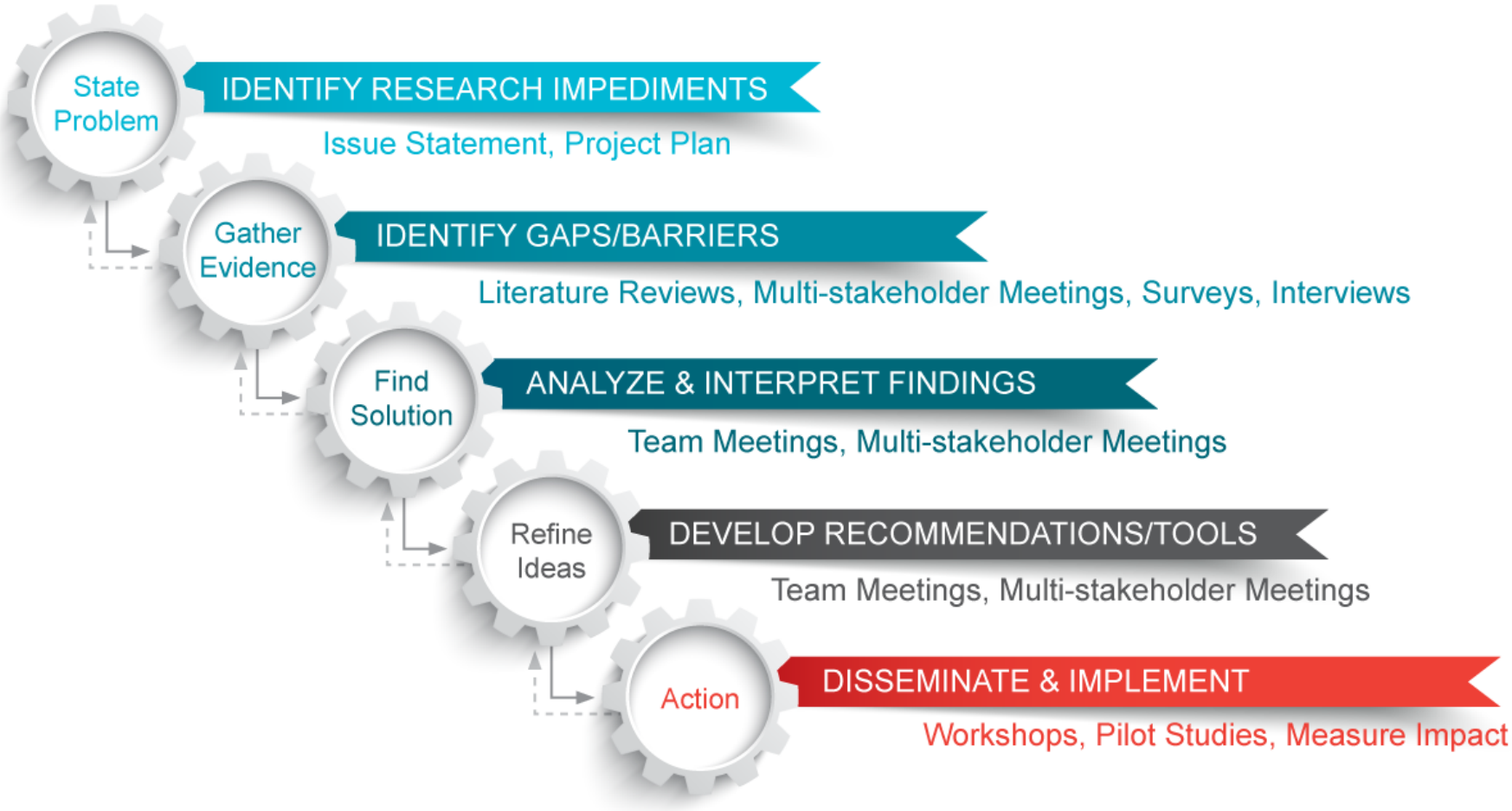
Enhance the quality of clinical trials without adding undue burden



Leverage new technologies to improve efficiency of clinical trials

Identify streamlined strategies to meet regulatory requirements

CTTI Methodology



Portfolio of CTTI Projects

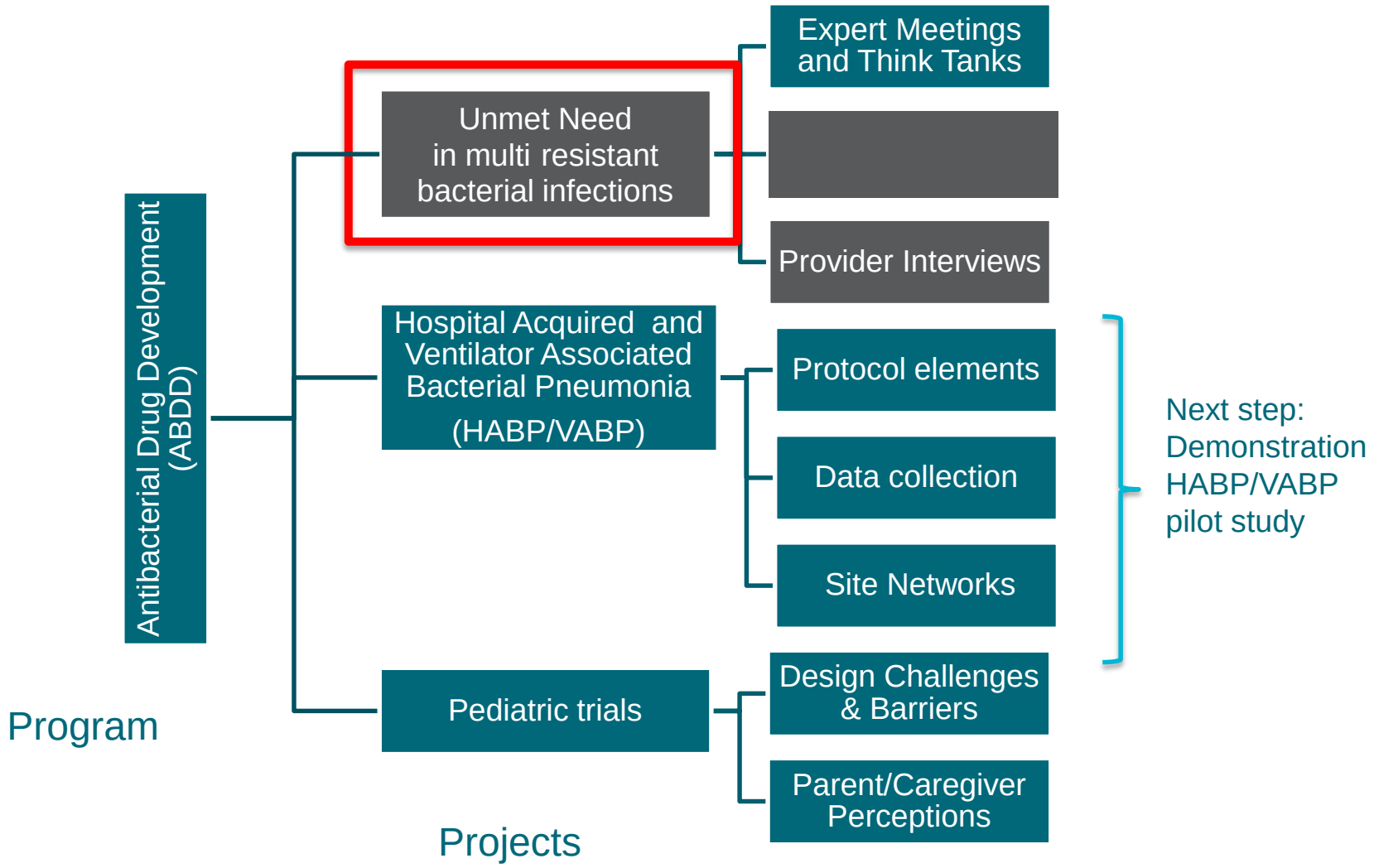
	Investigational plan	Study start up	Study conduct	Analysis and dissemination	Specialty areas
Completed projects	• Large simple trials • Uses of electronic data	• Central IRB • Site metrics	• Adverse event reporting • IND safety • Monitoring		• Long-term opioid data

CTTI Program: Antibacterial Drug Development (ABDD)

Background:

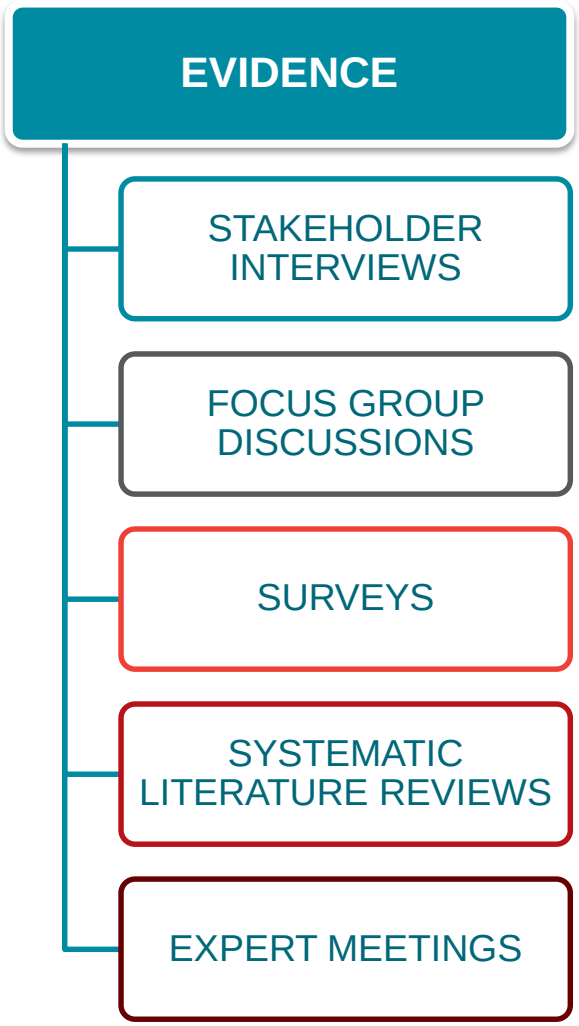
- Prevalence of antibacterial resistance continues to rise
- Pressing need for drug development in this area
- Resistant infections are a burden to society with serious consequences of morbidity and mortality and healthcare costs
- **In 2012, FDA established a task force and engaged CTTI and other organizations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

ABDD Program and Projects



Evidence guides the journey to solutions

- We use quantitative & qualitative research methods, selecting those best aligned with each project's objectives, to:
  - Identify/describe "what is going on" to gain a better understanding of a particular phenomenon
  - Move beyond individual views to a more complete and objective understanding of the disincentives and motivators for change
- Equipped with data, we then challenge assumptions, identify roadblocks, build tools and develop recommendations to change the way people think about and conduct clinical trials.



Work-Stream 2 Team

- **Team Leaders:**
  - Thomas Holland (Duke)
  - Stephen Mikita (Patient Rep)
  - Rose Tiernan (FDA)
  - Joseph Toerner (FDA)

- **Team Members:**
  - Deborah Collyar (PAIR)
  - Carrie Dombeck (Duke)
  - Helen Donnelly (Northwestern)
  - Jeff Loutit (The Medicines Co.)
  - Jonas Santiago (FDA
  - Pamela Tenaerts (CTTI)
  - Edward Cox (FDA)
  - Kevin Weinfurt (Duke)
  - Vance Fowler (Duke)
  - Lisa LaVange (FDA)

Thank you.

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