Introduction to the Clinical Trials Transformation Initiative

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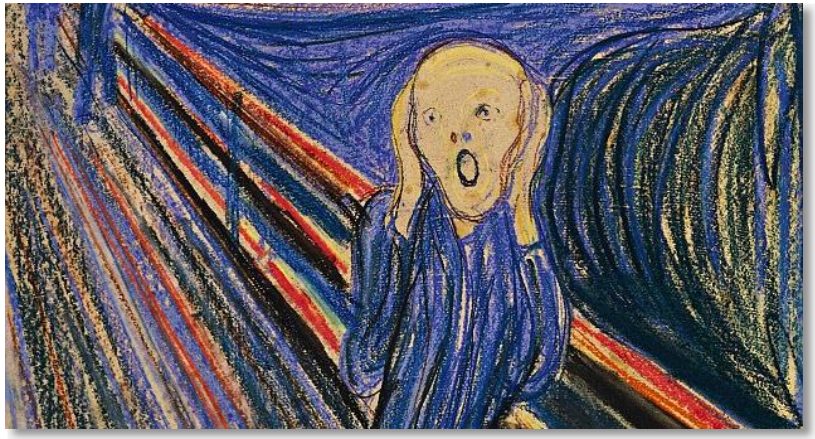
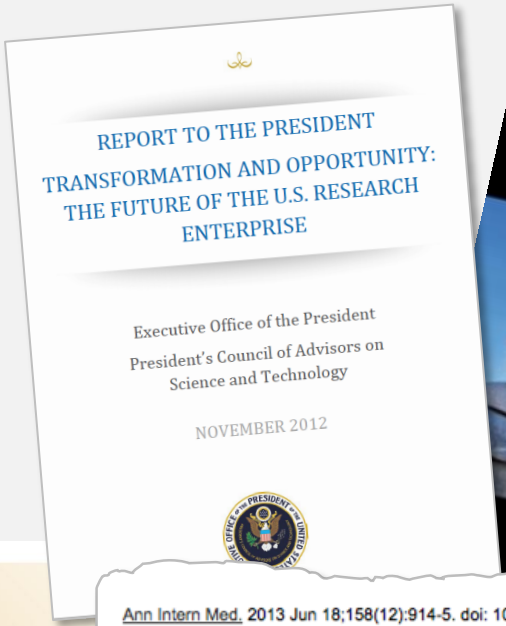
CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

March 30, 2016

Clinical trials in crisis



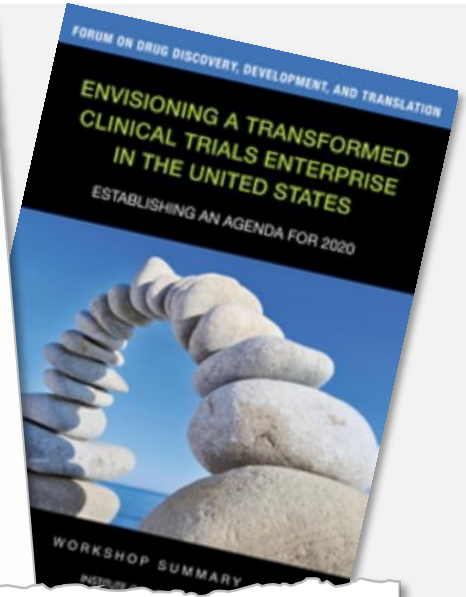

REPORT TO THE PRESIDENT

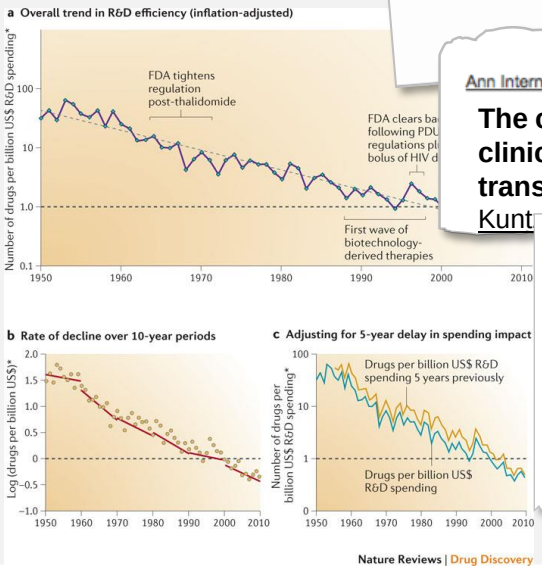
TRANSFORMATION AND OPPORTUNITY: THE FUTURE OF THE U.S. RESEARCH ENTERPRISE

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

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

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

ACI Clinical
Alexion
Amgen
AstraZeneca
Bard
Celgene
cempra
EMD Serono
Genentech – A Member of the Roche Group
GlaxoSmithKline
Johnson & Johnson
Lilly
medidata
Medtronic
Merck
Pfizer
Purdue
St. Jude Medical
Target Health Inc
The Medicines Company

AHRQ
BARDA
CDC
CMS
FDA
NIH
OHRP
Department of Veterans Affairs

ACRO
ACRP – Association of Clinical Research Professionals
AdvaMed
Bio
BRANY
CDISC
Chesapeake IRB
cirb
CITI Program
DIA
Greenleaf Health LLC
King & Spalding
MedStar Health Research Institute
MK&A
Palo Alto Investors
PhRMA
PMG Research
Quorum Review IRB
SCT – Society for Clinical Trials
SCRS
wcg – WIRB Copernicus Group

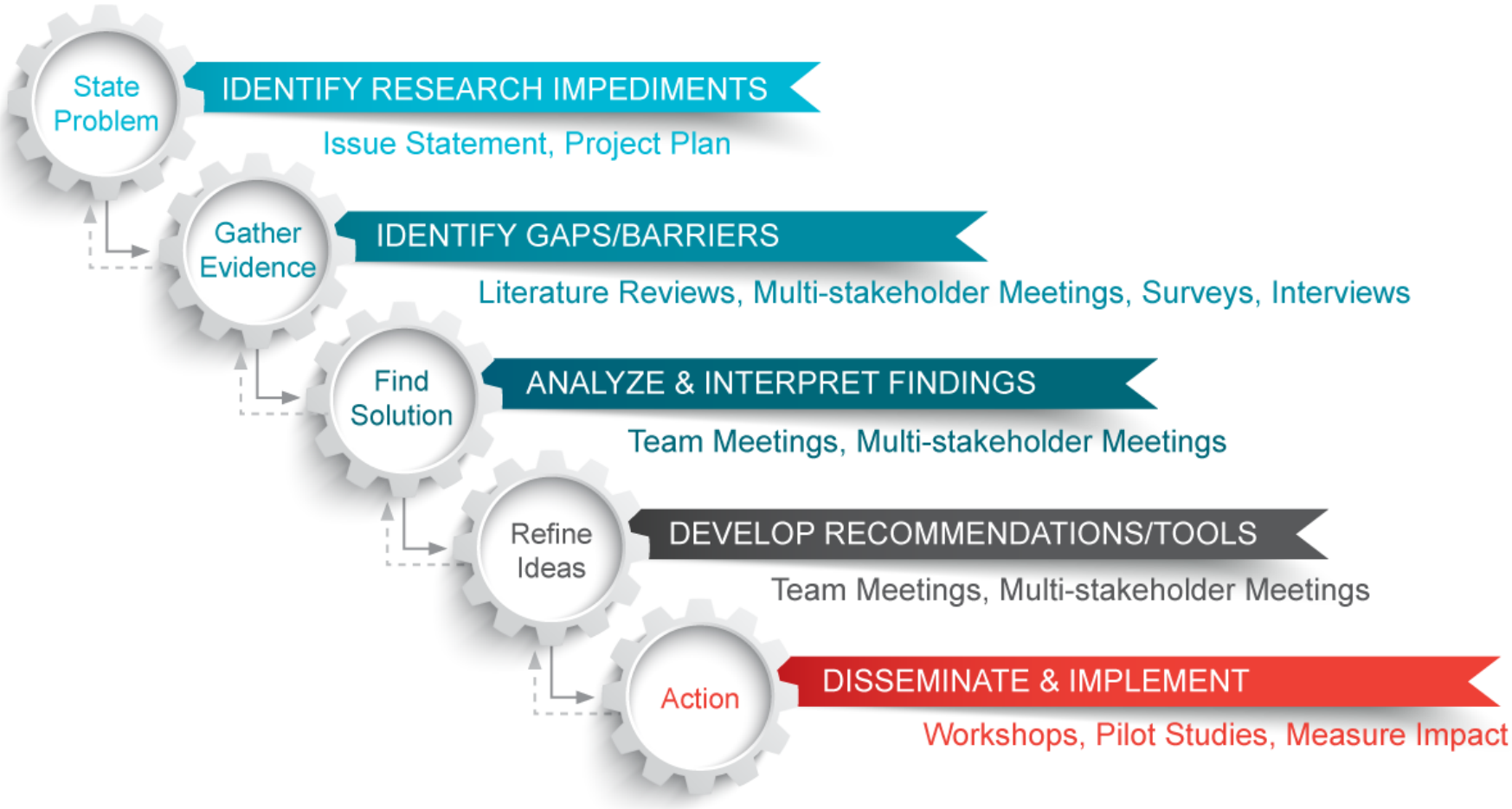
Alliance for Lupus Research
Crohn's & Colitis Foundation of America
Foundation for Prader-Willi Research
Friends of Cancer Research
JDRF
The Life Raft Group
Melanoma Research Alliance
The Michael J. Fox Foundation for Parkinson's Research
MPN Research Foundation
NORD
Parent Project Muscular Dystrophy
Parkinson's Disease Foundation
Pulmonary Fibrosis Foundation
Susan G. Komen

C5Research
Dana-Farber Cancer Institute
DukeMedicine
Feinstein Institute for Medical Research – Northwell Health
The George Institute for Global Health
KU Medical Center – The University of Kansas
Julius Clinical
Health Through Knowledge – PHRI
School of Medicine – University of Missouri Health System
UNC – The North Carolina Translational & Clinical Sciences Institute
University of Oxford
University of Rochester Medical Center
NYU Langone Medical Center
UW Health

How CTTI Works

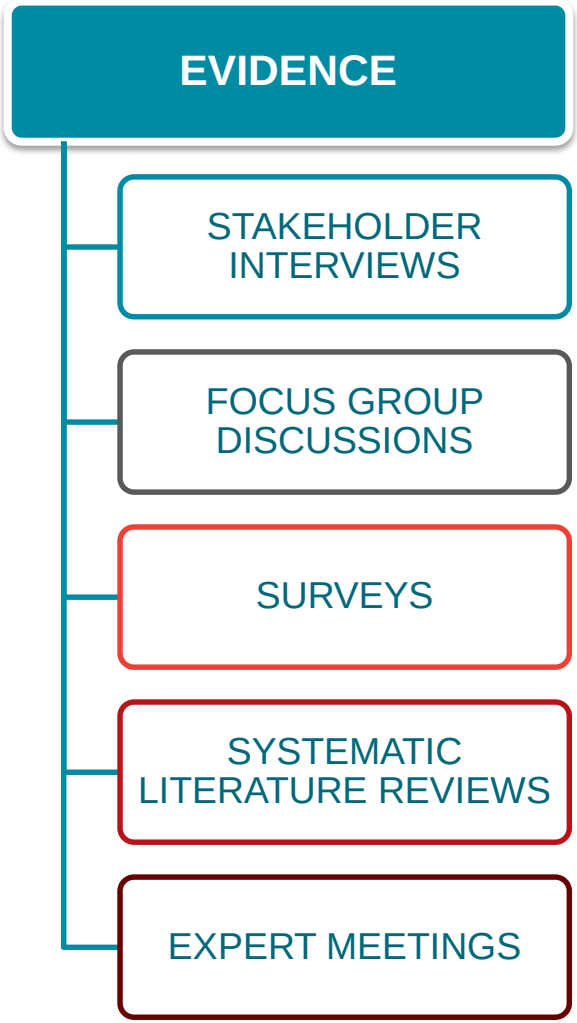
- Engage & value all stakeholders equally
- Understand incentives to maintain non-value added activities and have solutions that are mindful of those incentives
- Plant the seeds for change throughout all phases of a project
- Develop actionable, evidence-based, consensus driven recommendations
- Create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

CTTI Methodology



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.

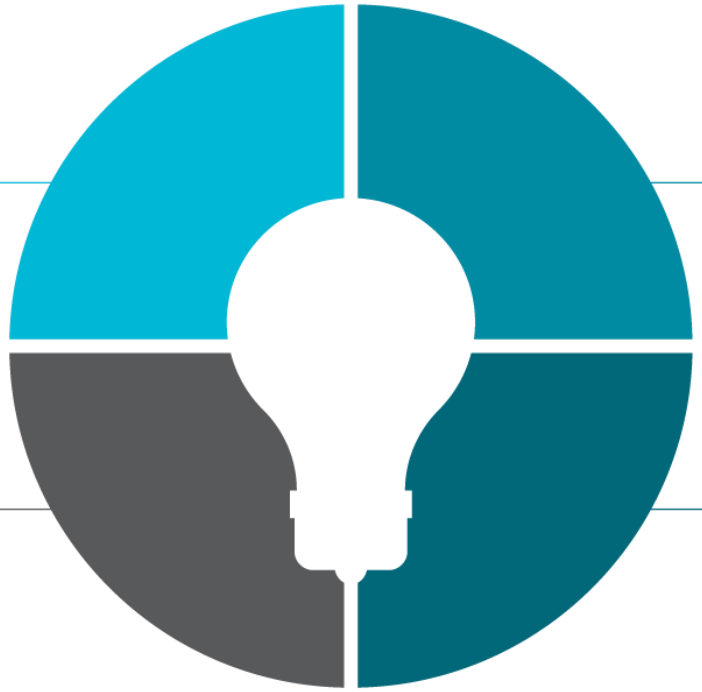


CTTI Recommendations

- 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

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

Registry Trials Project Team

- **Team Leaders:**
  - John Laschinger (FDA/CDRH)
  - Theodore Lystig (Medtronic)
  - James Tcheng (Duke)

- **CTTI Project Managers:**
  - Steve Mikita (Patient Advocate)
  - Sara Calvert (CTTI)

- **Team Members:**
  - Lauren McLaughlin (MJFF)
  - Chunrong Cheng (FDA/CBER)
  - Alan Clucas (Galderma)
  - Christopher Dowd (CFF)
  - E. Dawn Flick (Celgene)
  - Nicolle Gatto (Pfizer)
  - Kristen Miller (FDA/CDER)
  - Daniel Mines (Merck)
  - Jules Mitchel (Target Health)
  - Magnus Petersson (AstraZeneca)
  - Sunil Rao (Duke)
  - Arlene Swern (Celgene)
  - Emily Zeitler (Duke)

Thank you.

CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

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