

Welcome to the CTTI Informed Consent Project Expert Meeting

March 10-11, 2015



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

Housekeeping

- Please remember to turn your phones on vibrate or silent
- Please state your name and organization prior to speaking so others know who is talking
- Parking
- Restrooms
- Lunch
- Reception

Introduction to The Clinical Trials Transformation Initiative

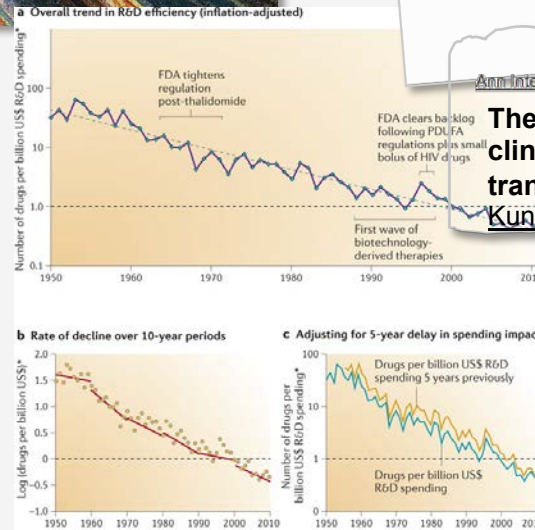
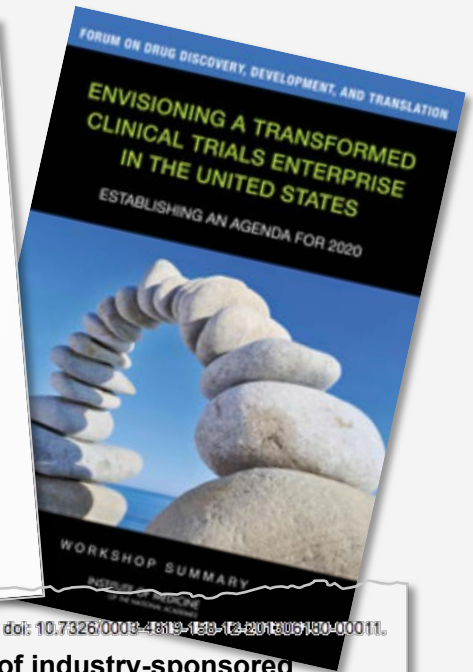
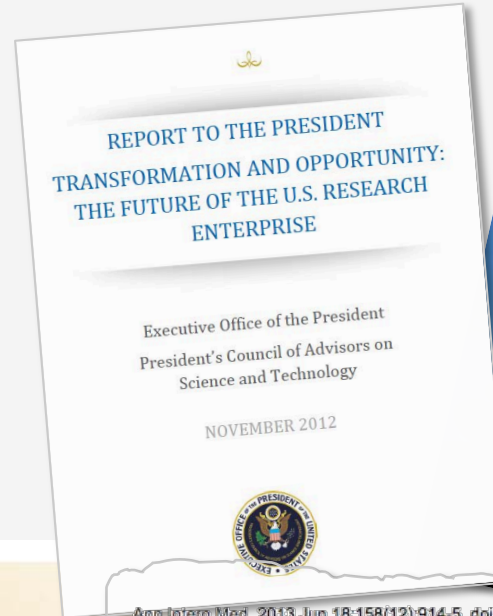
Matthew Harker, CTTI

March 10, 2015



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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 RF

BROOKINGS

RESEARCH ▾

EVENTS

EXPERTS

ABOUT ▾

MAR
5

PAST EVENT

Biomedical Innovation: Identifying Challenges and Prioritizing Needs

Nature Reviews | Drug Discovery

Addressing This Need



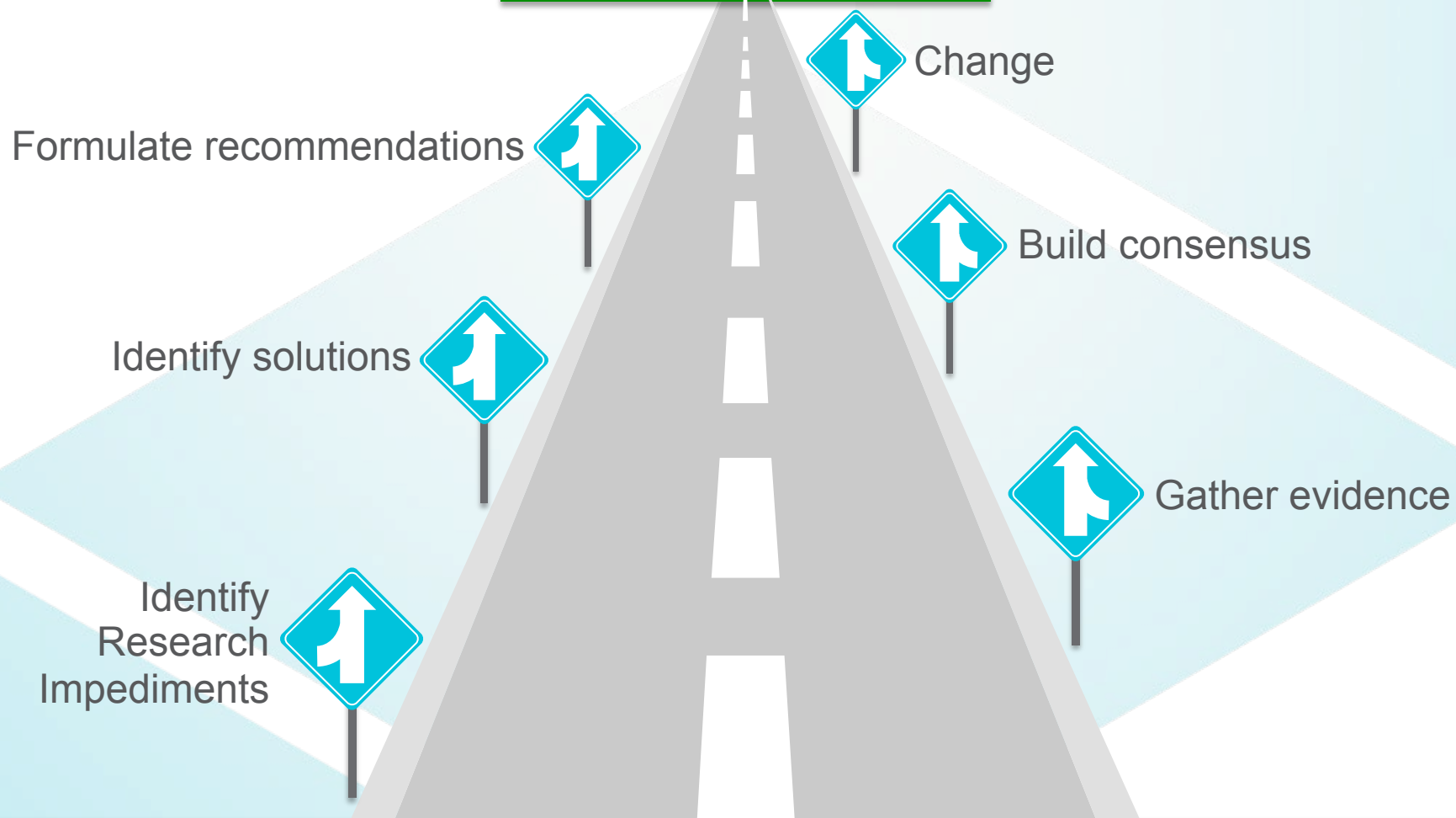
To identify and promote practices that will *increase the quality and efficiency* of clinical trials

Public-Private Partnership
involving all stakeholders
60+ members

Collaboration Towards Solutions



Better, Streamlined, Fit for Purpose Clinical Trials



Portfolio of CTTI Projects

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

Introduction to the CTTI Informed Consent Project

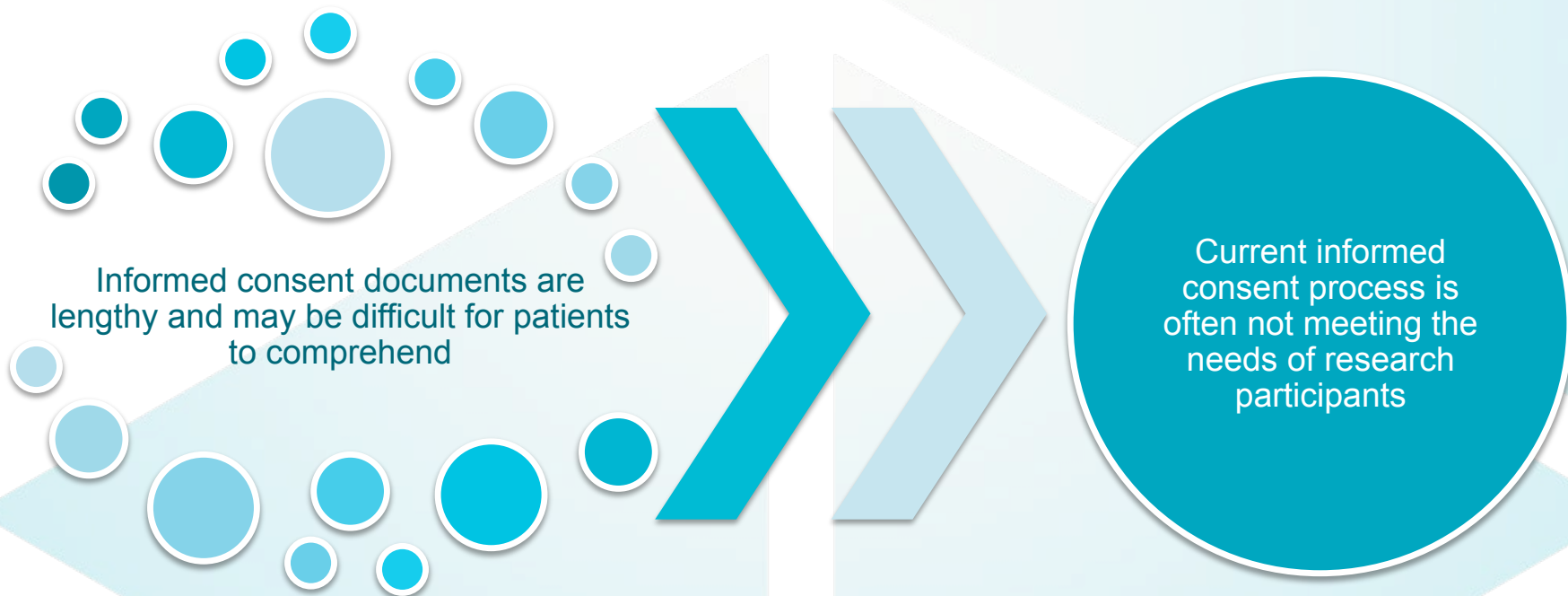
Michele Kennett, University of Missouri

March 10, 2015



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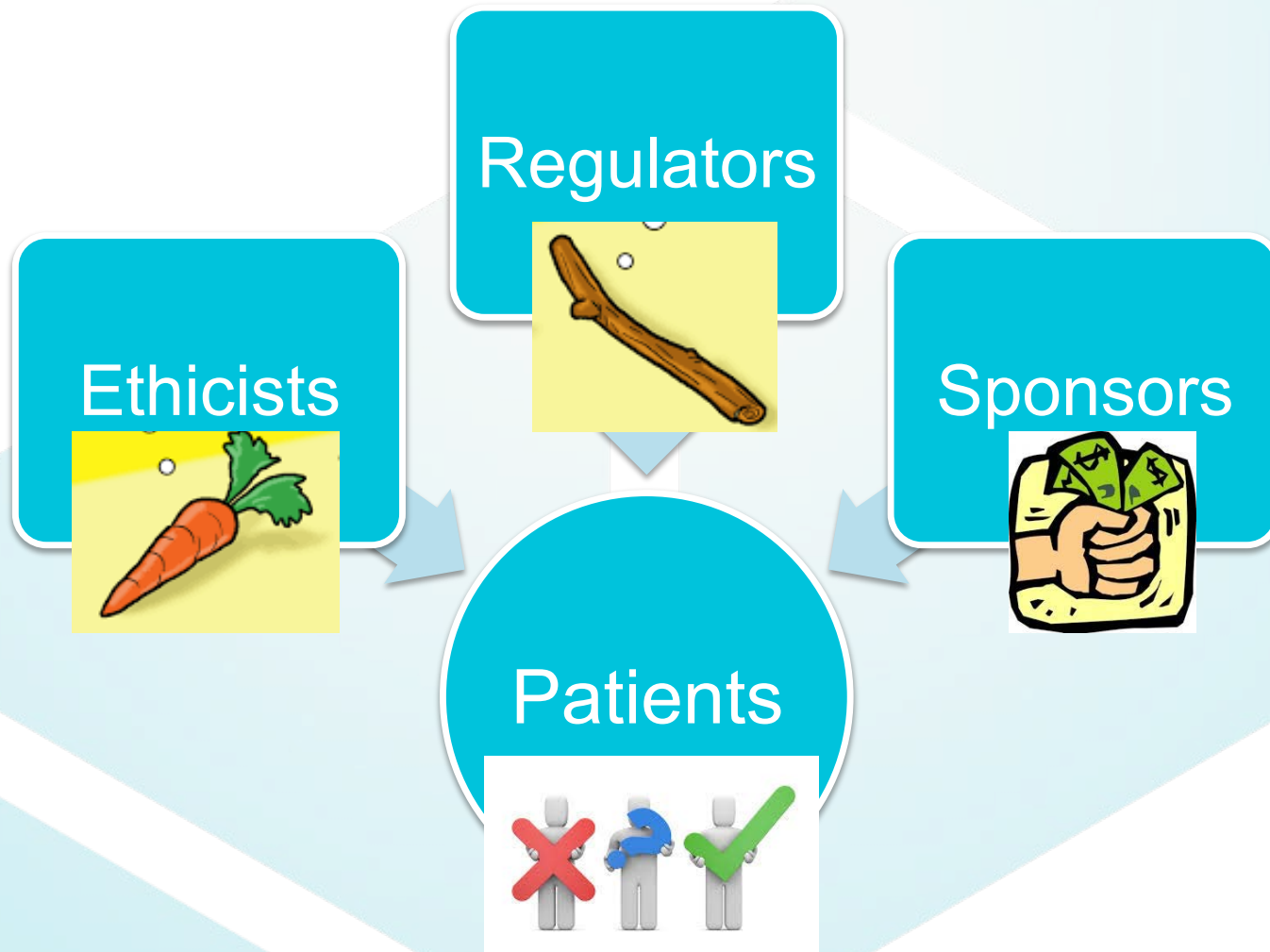
Issue




Informed consent documents are lengthy and may be difficult for patients to comprehend

Current informed consent process is often not meeting the needs of research participants

Why Improve Informed Consent?



Project Objectives

- 
- Understand previous and current efforts, whether successful or not, to improve informed consent documents and the informed consent process, including alternatives to the traditional paper informed consent document
 - Understand barriers and identify potential remedies to concisely communicating the required elements of informed consent
 - Propose a more effective process, including informed consent documentation, for ensuring research participants' understanding of critical informed consent elements, taking into account variability among research settings and participants
 - Identify potential strategies and opportunities for pilot testing the informed consent process improvement recommendations

**Re-consent of research participants, assent and consent in the learning health care system are outside the scope of this project*

Project Methods

Project Initiation

Literature Review

Expert Interviews

Develop Draft
Recommendations

Expert Meeting

Finalize
Recommendations

Project Team Members

TEAM LEADERS

- Michele Kennett, University of Missouri
- Jennifer Lentz, Eli Lilly and Company
- Jane Perlmutter, Patient Advocate

EXPERT INTERVIEW WORKGROUP LEADERS

- Beverly Lorell, King & Spalding
- Steve Mikita, Patient Advocate

CISCRP STAFF

- Annick Anderson
- Zachary Hallinan

CTTI STAFF

- Annemarie Forrest, CTTI Project Manager
- Kimberley Smith, Project Assistant

Project Team Members

- Fred Bloom (CDC)
- Steve Cummings (UCSF)
- Molly Flannery (FDA)
- Julia Gorey (OHRP)
- Jayvant Heera (Pfizer)
- Kevin Hudziak (Eli Lilly)
- Hallie Kassan (North Shore-LIJ)

- Kathy Kopnisky (NIH)
- Ross McKinney (Duke)
- Marsha Melvin (FDA)
- Linda Morgan (Patient Advocate)
- Seth Schulman (Pfizer)
- Sheila Young (GSK)
- Rose Tiernan (FDA)

Meeting Objectives

- Present findings and conclusions from the project literature review and expert interview series
- Solicit feedback and develop consensus on proposed recommendations to enhance the informed consent process

Meeting Agenda – Day 1

- Presentation of the literature review and expert interview findings
- Presentation and discussion on proposed recommendations related to
 - The Informed Consent Process
 - Training on Conducting the Informed Consent Process
 - Use of E-Consent Technology

Meeting Agenda – Day 2

- Presentation and discussion on proposed recommendations related to
 - The Tiered Consent Model for the Informed Consent Document
- Discuss actionable opportunities for transformative change in informed consent