CTTI 10 YEAR ANNIVERSARY

ONE DECADE OF IMPACT • ONE VISION AHEAD

CLINICAL TRIALS TRANSFORMATION INITIATIVE

June 12, 2018

The Clinical Trials Transformation Initiative One Decade of Impact, One Vision Ahead

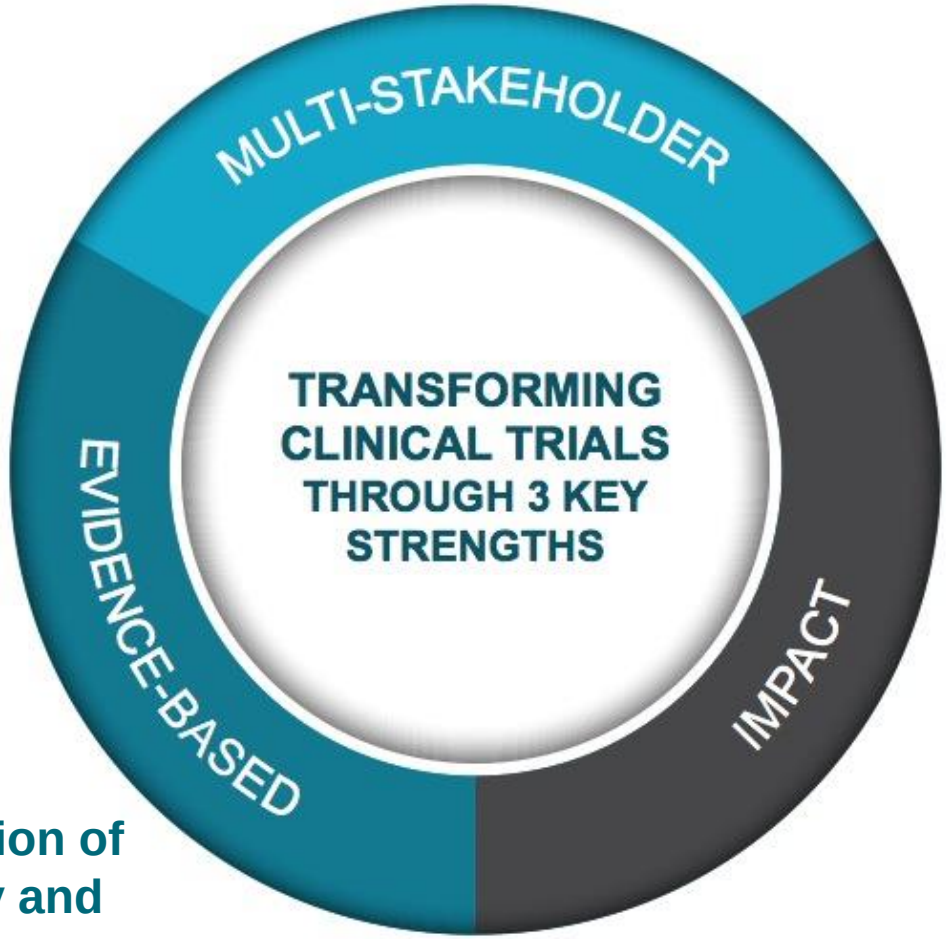
Pamela Tenaerts

Welcome!

- Restrooms: Out the doors and down the hallway to your left
- Parking: See staff at registration desk for vouchers
- Push to talk microphones
- Please turn phones on vibrate or silent
- Please use room Wi-Fi not personal hotspot
- WiFi instructions:
    1. Connect to "**Hilton_Meeting**" wireless network
    2. Open your browser
    3. Enter Access Code: **CTTI2018!**

Improving Clinical Trials

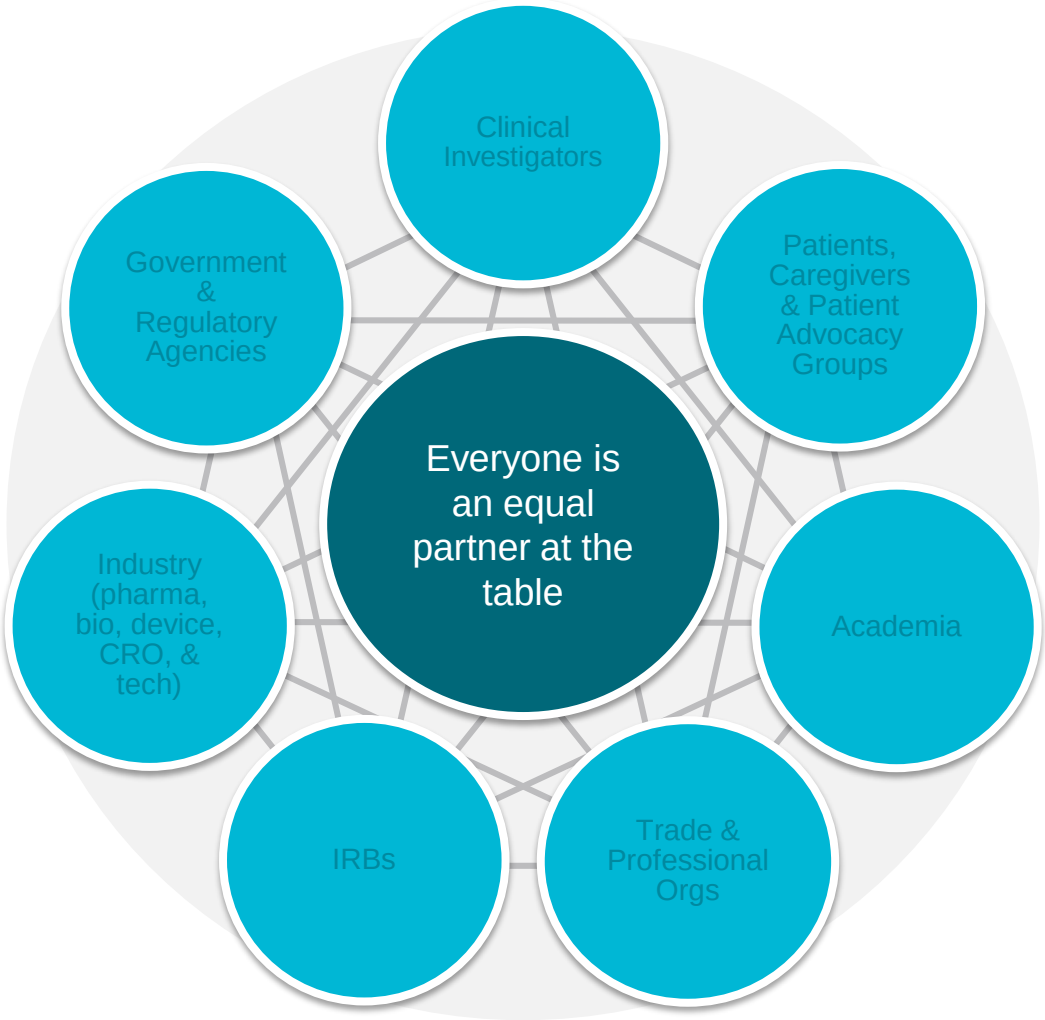
CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE



Public-Private Partnership
Co-founded by Duke University & FDA
Involves all stakeholders
80+ members

MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

Multi-Stakeholder



CTTI Membership

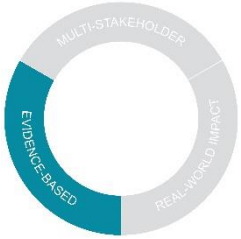
Abbott
ACI Clinical
ActiGraph
Alexion
Alnylam Pharmaceuticals
Amgen
BD
Boehringer Ingelheim
Celgene
rexahn Pharmaceuticals
EMD Serono
IMS Health & Quintiles are now IQVIA
Biogen
Syneos Health
Pfizer
GlaxoSmithKline
Johnson & Johnson
Lilly
medidata
Medtronic
Merck
Novartis
Genentech A Member of the Roche Group
Purdue
Target Health Inc
The Medicines Company

AHRQ
BARDA
CDC
CMS
FDA
NIH
OHRP
Department of Veterans Affairs

Crohn's & Colitis Foundation
CFFT DSMB
FasterCures A Center of the Milken Institute
CHDI Foundation
Foundation for Prader-Willi Research
Friends of Cancer Research
Lupus Research Alliance
Alpha-1 Foundation
Melanoma Research Alliance
Arthritis Foundation
The Michael J. Fox Foundation for Parkinson's Research
MPN Research Foundation
Parent Project Muscular Dystrophy
Parkinson's Foundation
Pulmonary Fibrosis Foundation
Susan G. Komen
The Life Raft Group
Women's Heart Alliance

Dana-Farber Cancer Institute
Duke Medicine
Julius Clinical
Yale
C5Research
The George Institute for Global Health
PHRI Health Through Knowledge
UNC The North Carolina Translational & Clinical Sciences Institute
KU Medical Center The University of Kansas
University of Oxford
University of Rochester Medical Center
NYU Langone Medical Center

ACRP
AdvaMed
wcg Wirb Copernicus Group
Bio
Northwell Health
Advarra
cirb
CITI Program
SCRS
DIA
King & Spalding
MedStar Health Research Institute
Palo Alto Investors
ASCO
PhRMA
PMG Research
Quorum Review IRB
SCT Society for Clinical Trials



Evidence-Based

- 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.

RESEARCH METHODS

- STAKEHOLDER INTERVIEWS
- FOCUS GROUP DISCUSSIONS
- SURVEYS
- SYSTEMATIC LITERATURE REVIEWS
- EXPERT MEETINGS

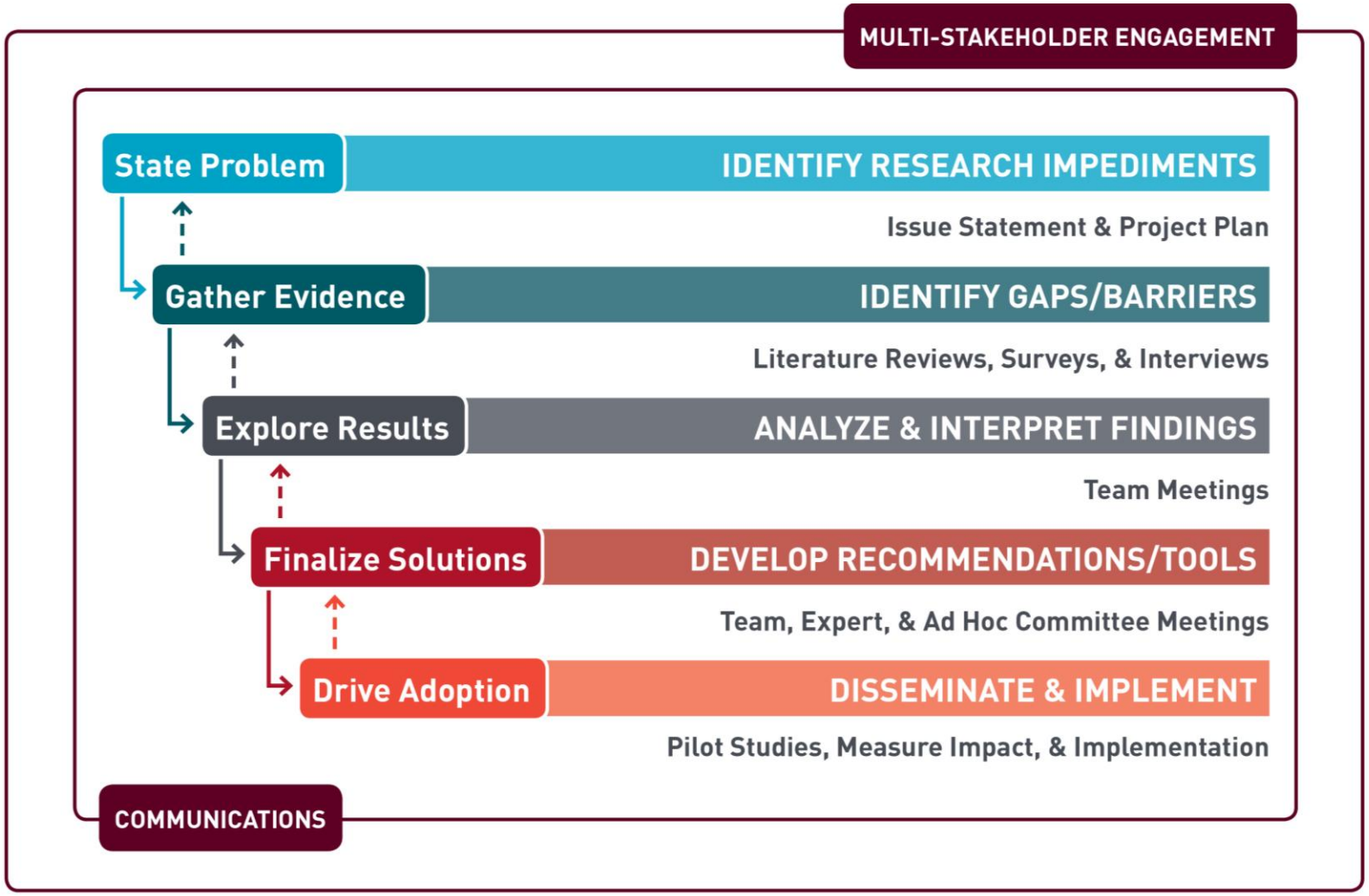
Examples of Real-World Impact within Organizations

- CTTI's Single IRB tools & recommendations are used by organizations such as the National Institute of Neurological Disorders and Stroke (NIH) and Northwell Health.
- CTTI's Quality by Design framework is used by organizations such as AstraZeneca, Duke Clinical Research Institute, The Medicines Company, PCORnet, Pfizer, Target Health Inc., and University of Oxford.
- The Cystic Fibrosis Foundation has applied CTTI's recommendations to improve its DMC operations.
- Eli Lilly is implementing CTTI's informed consent recommendations through their new e-consent model.
- UCB Bioscience is applying CTTI's recommendations to develop mechanisms for implementing patient engagement strategies across the drug development life cycle.

Real-World Impact at the Policy Level

- CTTI cited in:
  - EMA reflection paper
  - FDA guidance documents
  - ICH reflection paper
  - NIH draft policy
  - Congressional efforts around 21st Century Cures legislation

CTTI Methodology



CTTI Recommendations & Tools

- Streamline **Antibacterial Pediatric and HABP/VABP Trials**
- Organize **DMCs** to ensure patients' safety
- Move **Recruitment** planning upstream to reduce barriers to participation
- Develop a better **IND Safety Reporting** system
- Perform higher quality **Informed Consent** process
- Involve **Patient Groups** as equal partners
- Apply **Quality by Design (QbD)** principles to create better protocols
- Improve ethics review process via use of **Single IRB**
- Reduce inefficiencies of investigator **GCP Training**
- Use **Registries** to conduct more efficient clinical trials
- Identify the best pathways for developing **Novel Endpoints** generated by mobile technologies
- Create **Pregnancy Testing** plans for improved clinical trials
- Strengthen the **Site Investigator Community**

Project Portfolio

Areas of Strategic Focus:	SYSTEMATIC EVIDENCE GENERATION	PATIENTS AS EQUAL PARTNERS	EFFICIENT & QUALITY TRIALS	PUBLIC HEALTH CONCERN	SAFE & ETHICAL TRIALS
Active Projects:	MCT Decentralized Clinical Trials MCT Mobile Technologies MCT Stakeholder Perceptions Real World Evidence State of Clinical Trials		Investigator Qualification	ABDD HABP/VABP Studies	
Complete Projects (now driving adoption):					Single IRB, Single IRB Adv DMCs Informed Consent Pregnancy Testing IND Safety, IND Safety Adv SAE Reporting

Driving adoption priorities in green

THANK YOU.

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