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

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

Everyone is an equal partner at the table

- Clinical Investigators
- Government & Regulatory Agencies
- Industry (pharma, bio, device, CRO, & tech)
- IRBs
- Patients, Caregivers & Patient Advocacy Groups
- Trade & Professional Orgs
- Academia
- CTTI 10 YEAR ANNIVERSARY
  ONE DECADE OF IMPACT • ONE VISION AHEAD
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.
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.
CTTI cited in:

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

State Problem
- IDENTIFY RESEARCH IMPEDIMENTS
  - Issue Statement & Project Plan

Gather Evidence
- IDENTIFY GAPS/BARRIERS
  - Literature Reviews, Surveys, & Interviews

Explore Results
- ANALYZE & INTERPRET FINDINGS
  - Team Meetings

Finalize Solutions
- DEVELOP RECOMMENDATIONS/TOOLS
  - Team, Expert, & Ad Hoc Committee Meetings

Drive Adoption
- DISSEMINATE & IMPLEMENT
  - Pilot Studies, Measure Impact, & Implementation

COMMUNICATIONS

MULTI-STAKEHOLDER ENGAGEMENT
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**
  - MCT Decentralized Clinical Trials
  - MCT Mobile Technologies
  - MCT Stakeholder Perceptions
  - Real World Evidence
  - State of Clinical Trials

- **PATIENTS AS EQUAL PARTNERS**
  - Investigator Qualification

- **EFFICIENT & QUALITY TRIALS**
  - ABDD HABP/VABP Studies

- **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

## Complete Projects (now driving adoption):

- Single IRB, Single IRB Adv
- DMCs
- Informed Consent
- Pregnancy Testing
- IND Safety, IND Safety Adv
- SAE Reporting

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**Driving adoption priorities in green**

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**CTTI 10 YEAR ANNIVERSARY**

**ONE DECADE OF IMPACT • ONE VISION AHEAD**

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THANK YOU.

Pamela Tenaerts
pamela.tenaerts@duke.edu

www.ctti-clinicaltrials.org