

Clinical Trials Transformation Initiative (CTTI)





- **A public private partnership co-founded by Duke and FDA in late 2007**
- **All stakeholders involved**
- **To identify and promote practices that will increase the quality and efficiency of clinical trials**

Portfolio review

	Safety	Quality	Start-up	Design	Other
Complete	SAE reporting	Monitoring	C IRB Site Metrics		
Current	IND safety SAE case studies	QbD/QRM workshops		LST Pregnancy ABDD	CT.gov ABDD Mini Sentinel HAP/VAP pilot
2013			CIRB f/o Inf. Consent GCP Training Recruitment /retention		

Project Methodology

Identify
Research
Impediments

Gather
Evidence

- Surveys
- Literature review
- Data analysis
- Focus groups
- interviews

Analyze data
Consensus

- Workshops
- Expert meetings

Formulate
Recommendations

- Workshops
- Presentations
- Publications
- Posters

Promote
implementation

- Continuation projects
- Workshops
- Pilot studies
- Stakeholder engagement

Key Accomplishments

- Generated evidence and formulated implementable recommendations
- Created an inclusive forum that is influencing policy
- Increased patients' voice to improve clinical research
- Raised questions about the portfolio of clinical trials as it relates to public health needs

Why CTTI Works

“Because of the broad array of engaged stakeholders, CTTI is in a unique position to drive major changes in the clinical trial system in the midst of massive global reforms.”

*Rachel Sherman, M.D.,
Director for the Office of Medical Policy at the FDA's CDER
Co-chair of the CTTI Executive Committee*