

# Clinical Trials Transformation Initiative (CTTI)



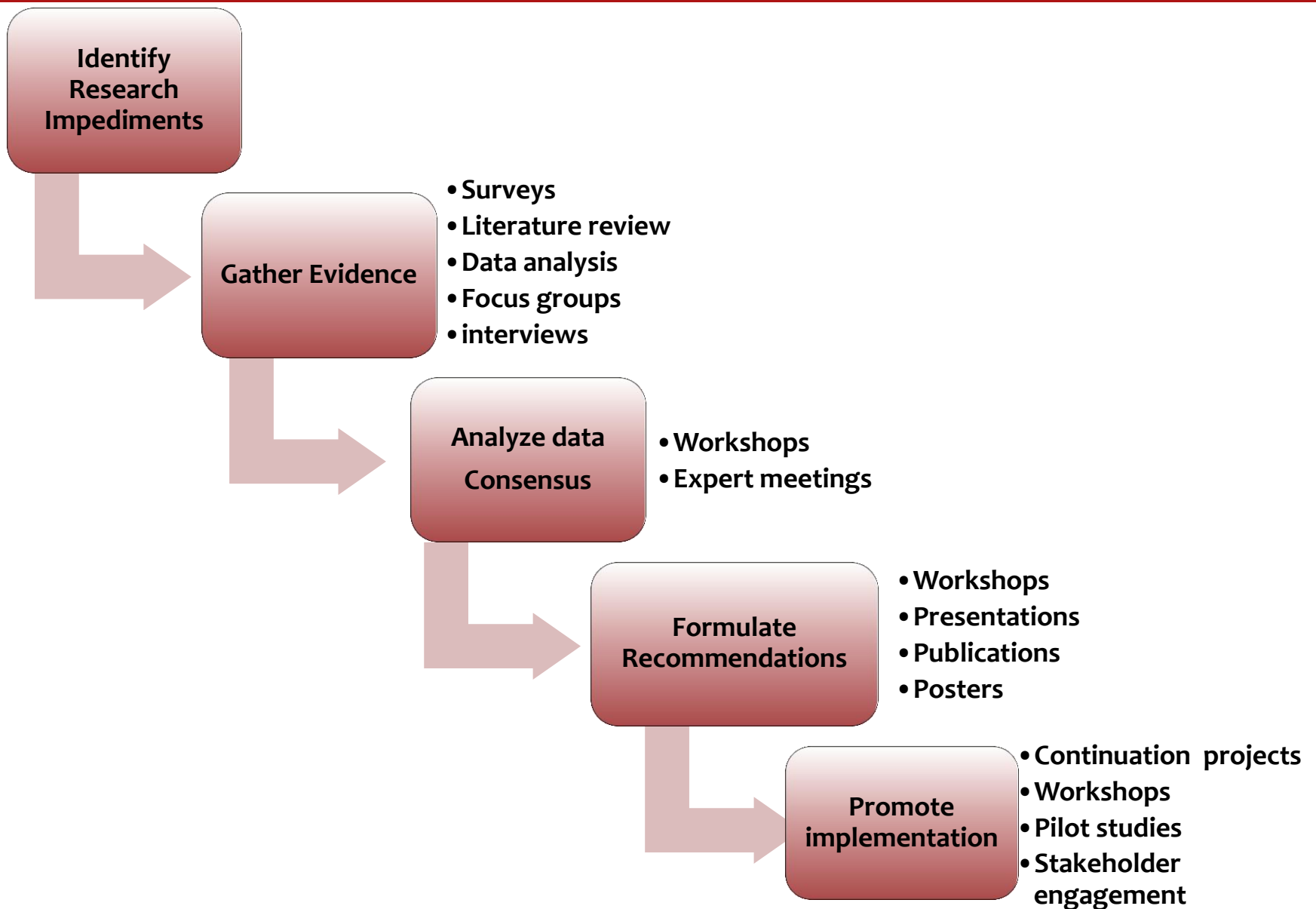


- **A public private partnership co-founded by Duke and FDA in late 2007**
- **All stakeholders involved**
- **To identify and promote practices that will increase the quality and efficiency of clinical trials**

# Portfolio review

	Safety	Quality	Start-up	Design	Other
Complete	SAE reporting	Monitoring	Central IRB Site Metrics		

# Project Methodology



# 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*

# Thank you!

- Speakers
- Survey respondents
- Meeting participants
- Team Members
- Team Leaders