

# Clinical Trials Transformation Initiative (CTTI)



# Welcome

- The Clinical Trials Transformation Initiative is hosting this meeting to facilitate a broad scientific discussion about optimal ways to generate additional evidence to help inform the safe and effective use of extended-release and long-acting opioid analgesics for chronic non-cancer pain.

# Housekeeping

- Meals – Elm 1 & 2, Breaks – in foyer
- Parking vouchers – see registration desk
- Sessions are being recorded
- Teleconference attendees
- Wireless log on and password on tables
- Materials provided: agenda, participant list, efficacy protocol synopsis
- Please state name and organization prior to posing question/comment



## How to use the push to talk microphones

- Push and release the middle white button
  - Please do not hold down the button for an extended time, this will cause the microphones to reset.
- Only push the microphone button when ready to speak.
  - Do not use the button/light to be called upon, only 4 can be activated at 1 time.

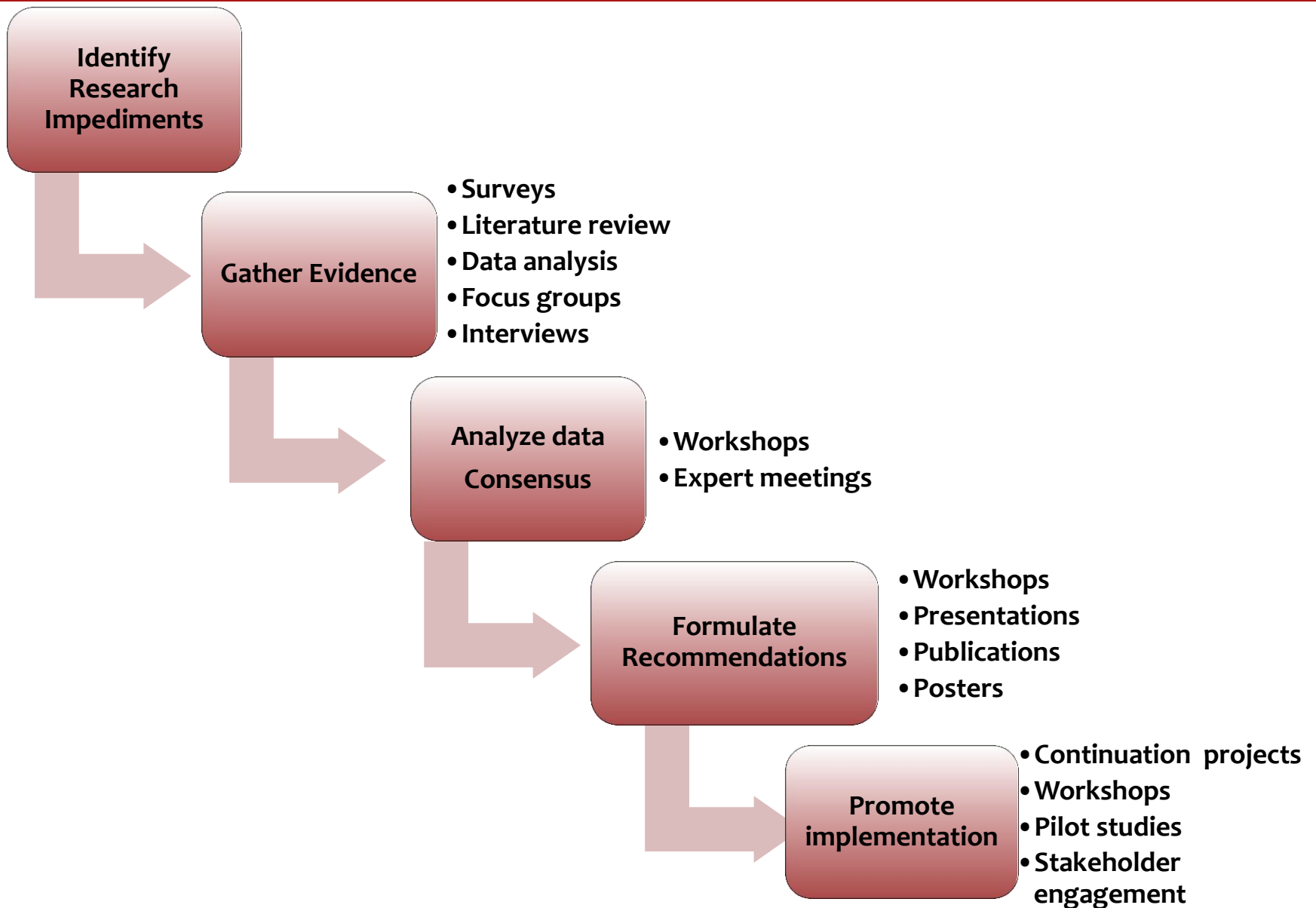


- **A public private partnership co-founded by Duke and FDA in late 2007**
- **All stakeholders involved**
- **To identify and promote practices that will increase the quality and efficiency of clinical trials**

# 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*