



CLINICAL  
TRIALS  
**TRANSFORMATION**  
INITIATIVE

*January 31, 2014*

# **GCP training Expert Meeting**

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# Clinical Trials Transformation Initiative

- Established by Duke University and the FDA as a public-private partnership in 2007
- All stakeholders working together to improve the clinical trials enterprise

## Mission

- To identify and promote practices that will increase the quality and efficiency of clinical trials

## Vision

- A high quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based prevention and treatment options

[www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org)

# CTTI Membership



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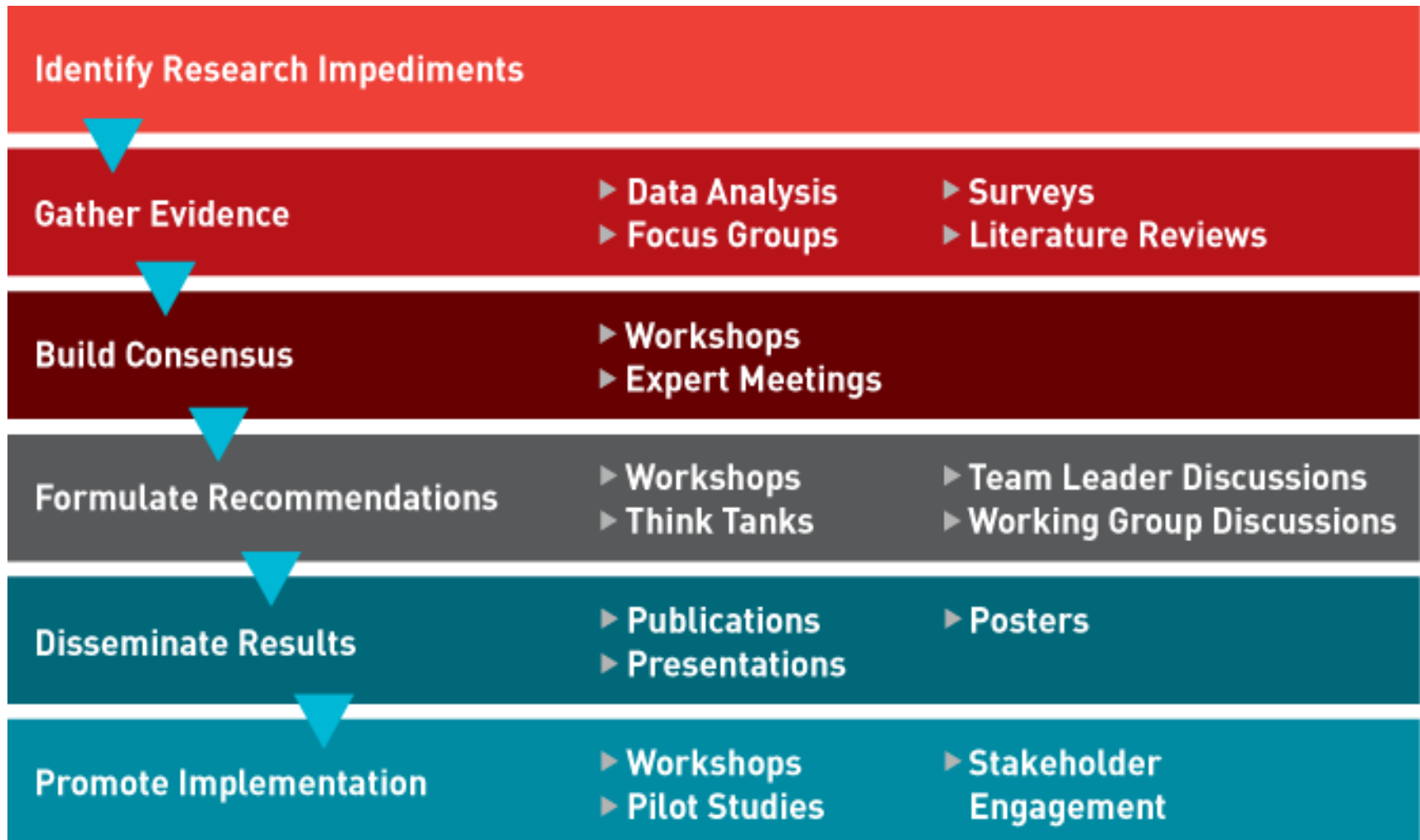


# Strategy

- Identify and shape potential transformational changes to the system
- Seek incremental improvements to current system
- Consider portfolio improvements of clinical trials being done relative to public health needs



# Methodology



# GCP Training Project

## Objective

- To improve the efficiency of GCP training imparted to investigators and site personnel conducting clinical trials

## Deliverables

- Summary of current practices and issues related to GCP training
- Recommendations on key elements of GCP training content and frequency
- Recommendations to facilitate a more efficient GCP training process

## Anticipated Impact

- Improving the efficiency and reducing the cost of clinical trials by streamlining the GCP training requirements

# GCP Training Working Group

- ▶ Jamie Arango (CITI)
  - ▶ Tina Chuck (North Shore- LIJ Health System)
  - ▶ Susan Ellenberg, (U Penn)
  - ▶ Bridget Foltz, (FDA-OGCP)
  - ▶ Colleen Gorman (Pfizer)
  - ▶ Heidi Hinrichs (St Jude)
  - ▶ Susan McHale (AZ)
  - ▶ Stephanie Shapley, (FDA- OMP)
  - ▶ Jonathan Seltzer, (ACRP & ACI)
- Project Manager: Kunal Merchant (CTTI)

# Literature review conducted by:

Evidence Synthesis Group, Duke Clinical Research Institute

 Megan Chobot

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 Gillian Schmidler Liz Wing

# THANK YOU.



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