



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

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



CTTI MEMBERS

www.ctti-clinicaltrials.org



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

CTTI Project Roster 2014

Incremental Improvements

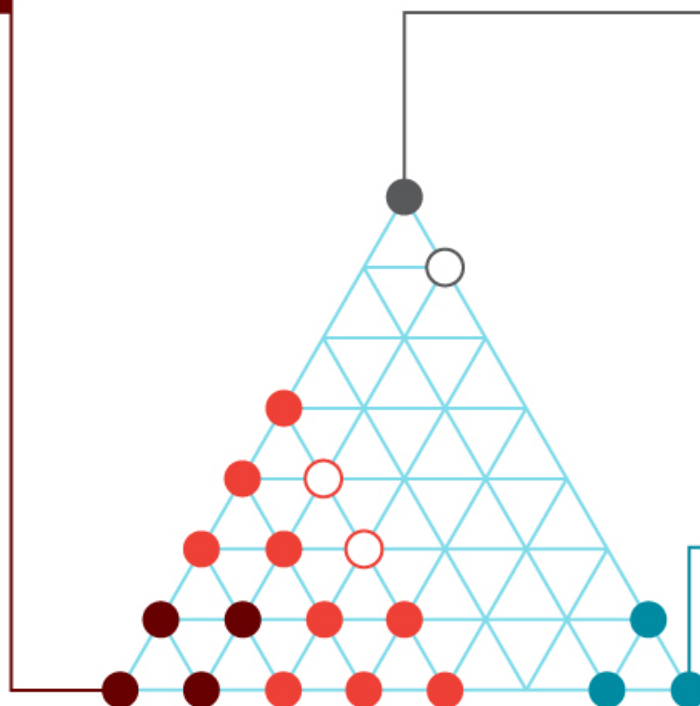
- ▶ Central IRB
- ▶ IND Safety
- ▶ Monitoring
- ▶ SAE Reporting
- ▶ Central IRB Advancement
- ▶ GCP Training
- ▶ Informed Consent
- ▶ Large Simple Trials
- ▶ Patient Groups & Clinical Trials
- ▶ Pregnancy Testing
- ▶ QbD & QRM
- ▶ Recruitment & Retention
- ▶ Site Metrics
- ▶ Data Monitoring Committees
- ▶ Site Performance & Quality

Transformational Improvements

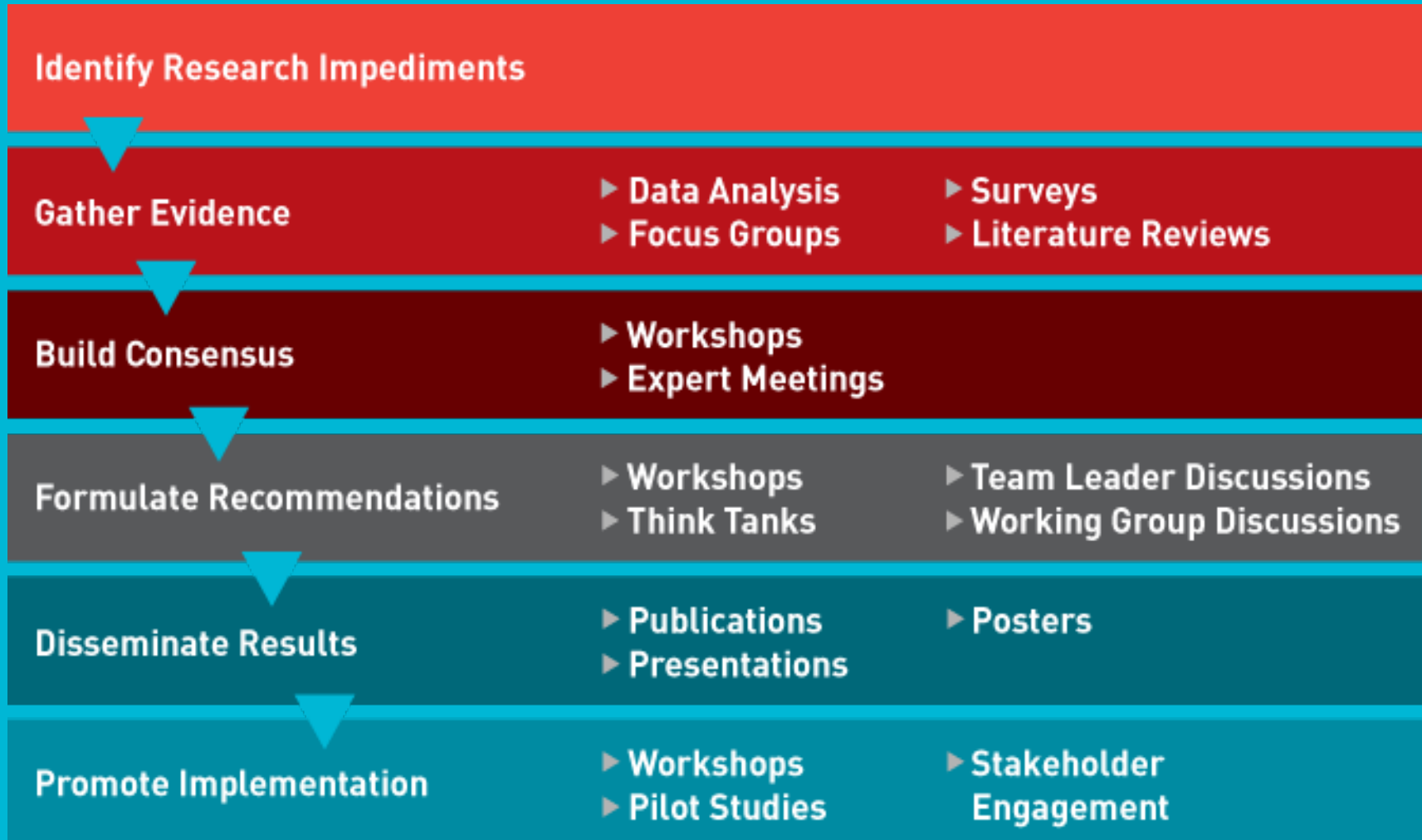
- ▶ Uses of Electronic Data
- ▶ Trials Using Data Registries

Portfolio Improvements

- ▶ Antibacterial Development
- ▶ Long-Term Opioid Data
- ▶ State of Clinical Trials



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
- ▶ Amy Kendrick
- ▶ Gillian Schmidler
- ▶ Liz Wing