CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

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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


Acurian
AMGEN
AstraZeneca
Bristol-Myers Squibb
Celgene
cempra
CEREXA
BAIRD
Lilly
EMD Serono
Genentech
A Member of the Roche Group
gsk
GlaxoSmithKline
Johnson & Johnson
OREXIGEN
Pfizer
PURDUE
St. Jude Medical
Target Health Inc
THE MEDICINES COMPANY
AHRQ
CDC
CMS
FDA
NATIONAL INSTITUTES OF HEALTH
OHRP
OFFICE FOR HUMAN RESEARCH PROTECTIONS
Department of Veterans Affairs
APCR
Academy of Physicians in Clinical Research
ACRO
ACRP
AdvaMed
AVOCA
THE AVOCA GROUP
Bio
Biotechnology Industry Organization
BRANY
CDISC
CHESAPEAKE IRB
cirb
CITI PROGRAM
copernicus group
DIA
HDRC
KING & SPALDING
MedStar Health Research Institute
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KU MEDICAL CENTER
The University of Kansas
NYU Langone
MEDICAL CENTER
Population Health Research Institute
THE GEORGE INSTITUTE
for Global Health
UCDAVIS
SCHOOL OF MEDICINE
CTSI
School of Medicine
University of Missouri Health System
UNC
HEALTH CARE
UNIVERSITY OF OXFORD
Penn
UNIVERSITY of ROCHESTER
MEDICAL CENTER
UWHealth

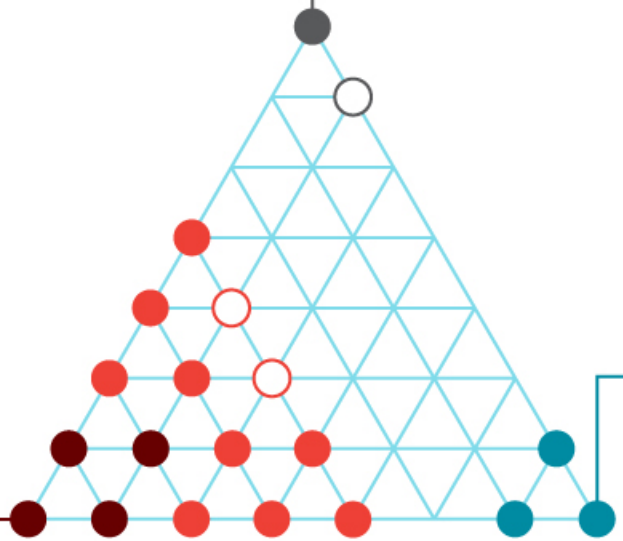
Strategy

- 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



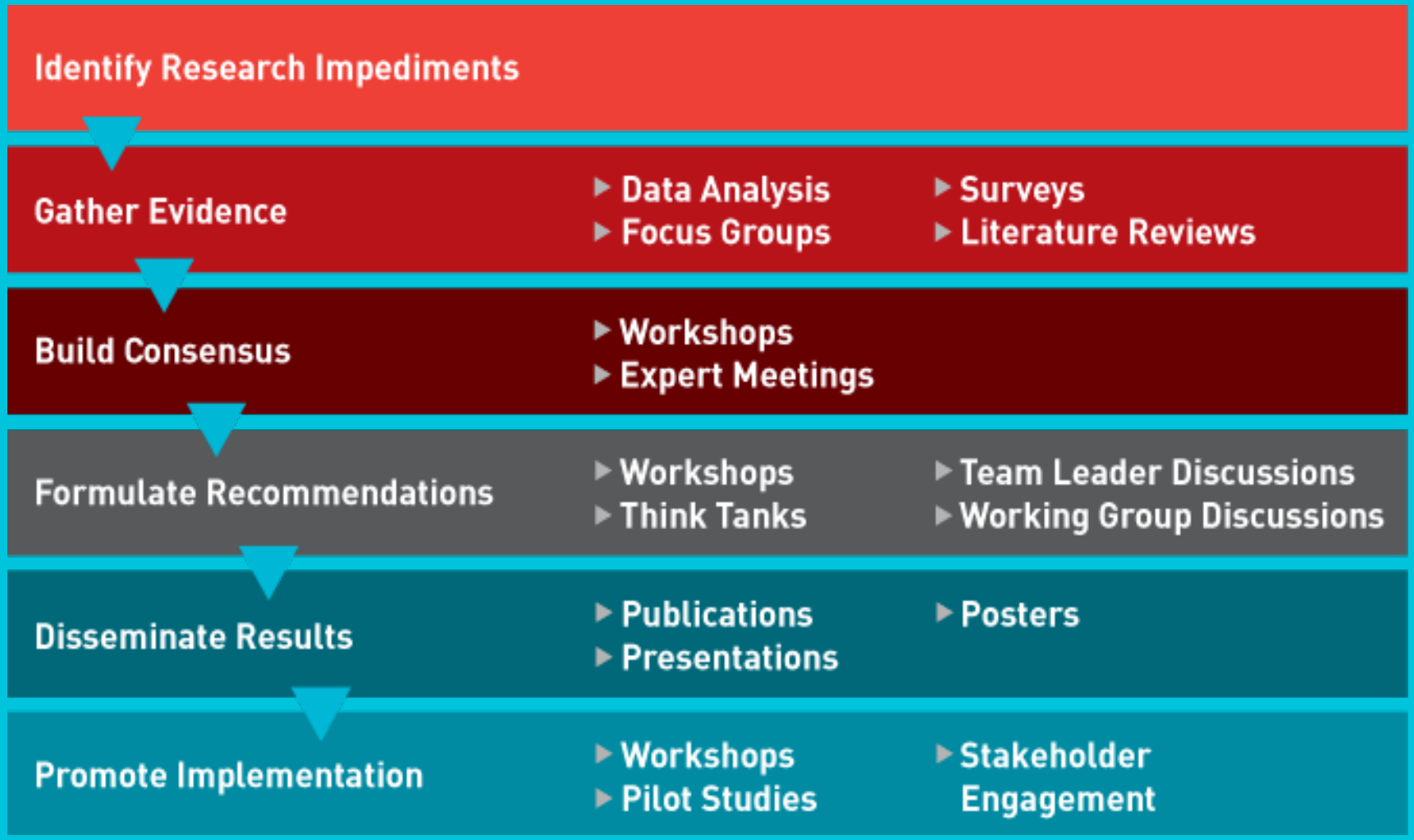
Transformational Improvements

- Uses of Electronic Data
- Trials Using Data Registries

Portfolio Improvements

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

Methodology



Quality by Design (QbD) & Quality Risk Management (QRM)

Monitoring Recommendations

Quality needs to be built into the design and conduct of trials

Monitoring approach for a given clinical trial should be tailored to the needs of that trial

Adoption

QbD principles document

Workshops to teach QbD and QRM and allow stakeholders to practice using the principles document

Anecdotes that industry is adopting

Anticipated Impact

Clinical trials will be more streamlined, fit for purpose and quality driven focusing on the absence of errors that matter

Team Leaders

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