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
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

Identify Research Impediments

Gather Evidence
- Data Analysis
- Focus Groups
- Surveys
- Literature Reviews

Build Consensus
- Workshops
- Expert Meetings

Formulate Recommendations
- Workshops
- Think Tanks
- Team Leader Discussions
- Working Group Discussions

Disseminate Results
- Publications
- Presentations
- Posters

Promote Implementation
- Workshops
- Pilot Studies
- Stakeholder Engagement

www.ctti-clinicaltrials.org
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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Special thanks to the Expert Working Group

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