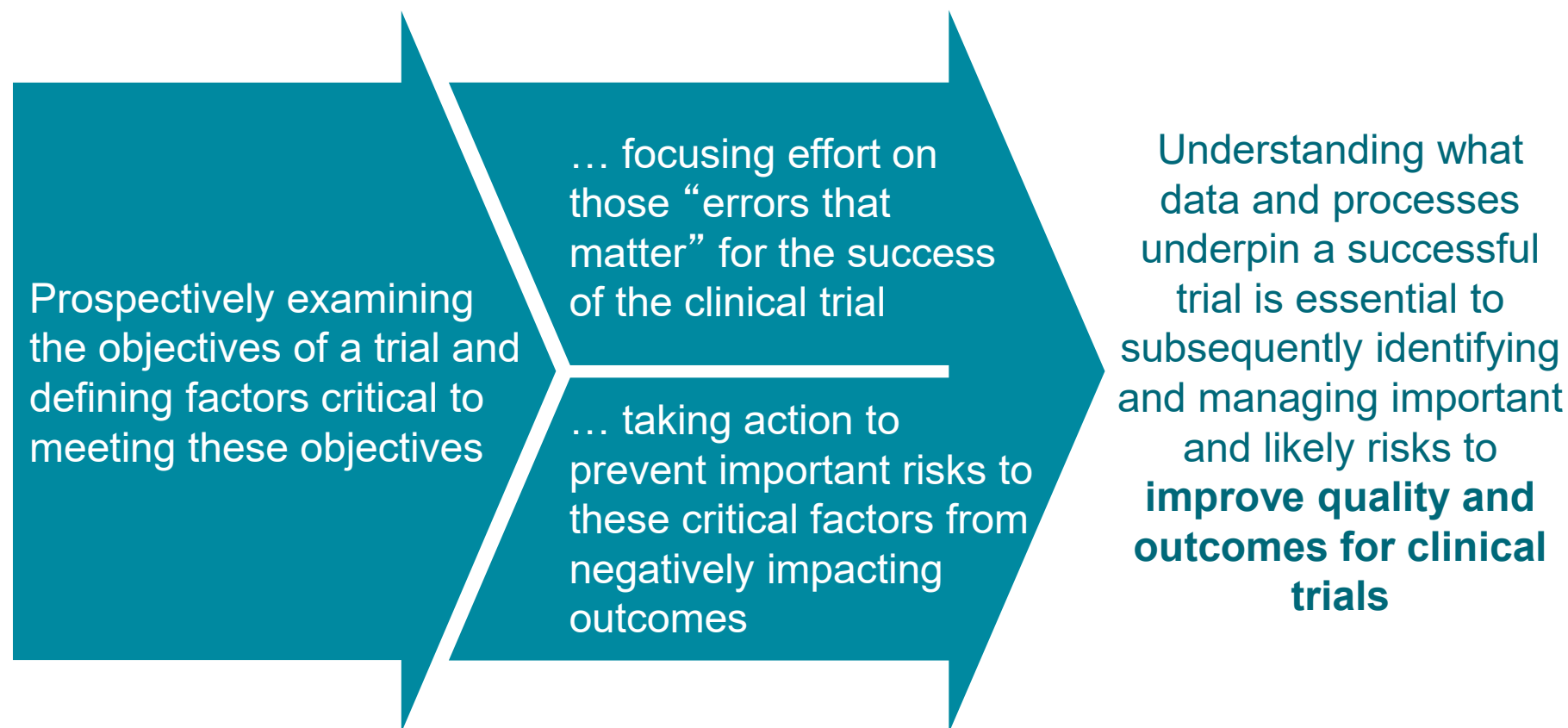# What Is Quality by Design?
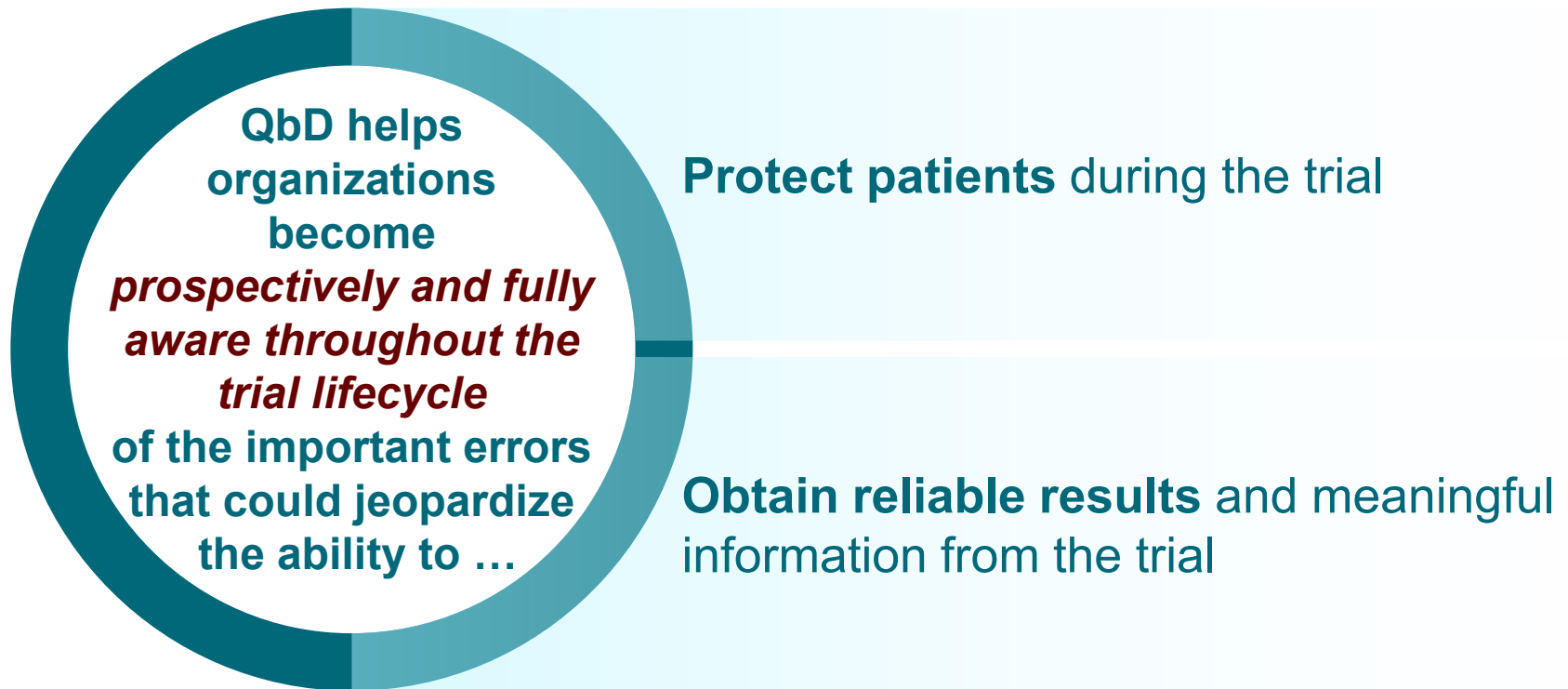

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Quality by Design: QbD Defined

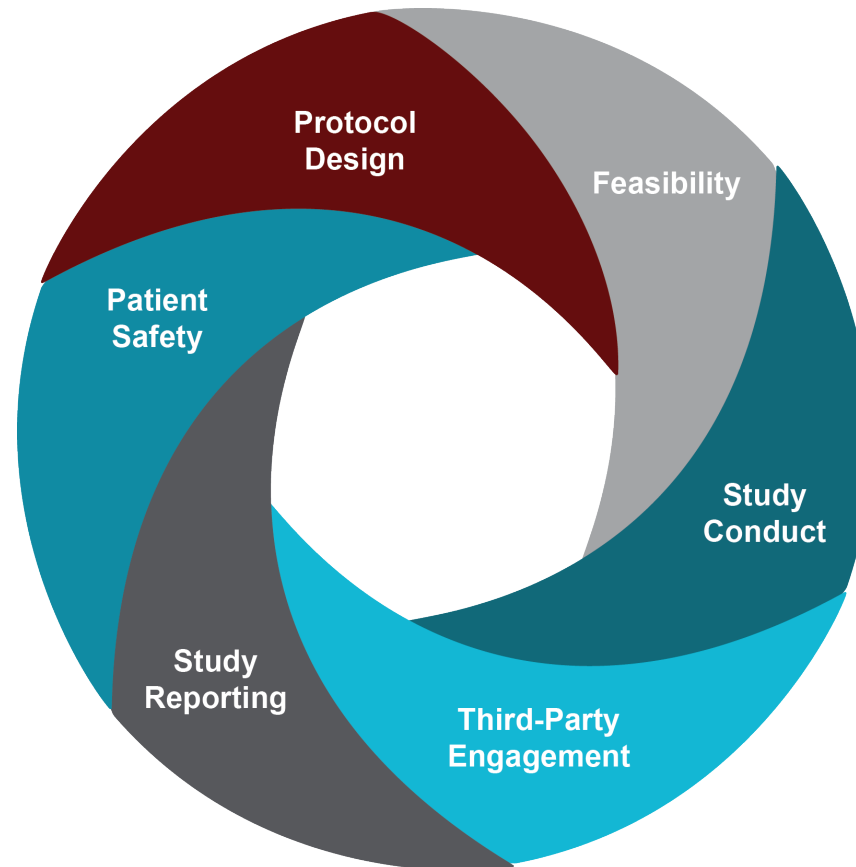**"Quality" in clinical trials is defined as the absence of errors that matter**

Prospectively examining the objectives of a trial and defining factors critical to meeting these objectives

… focusing effort on those "errors that matter" for the success of the clinical trial

… taking action to prevent important risks to these critical factors from negatively impacting outcomes

Understanding what data and processes underpin a successful trial is essential to subsequently identifying and managing important and likely risks to **improve quality and outcomes for clinical trials**

CTTI

How QbD Improves Clinical Trials

QbD helps organizations become *prospectively and fully aware throughout the trial lifecycle* **of the important errors that could jeopardize the ability to …**

Protect patients during the trial

Obtain reliable results and meaningful information from the trial

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QbD Step 1

Identify "critical to quality" factors (CTQs) for your specific trial

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QbD Step 2

Discuss potential risks related to
each CTQ identified that impact study quality
(i.e., participant safety or credibility of results)

QbD Step 3

Mitigate those risks that will likely lead to errors that matter and determine how to rapidly identify and react when there is an issue

CTTI

QbD Implementation Tool: CTTI Principles Document
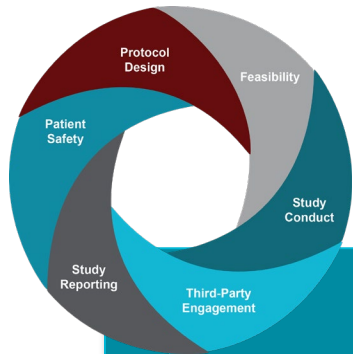
The Principles document is a resource that facilitates critical thinking and quality planning. It helps organizations gain a clear understanding of events that can …

… impede the conduct of the study

… place subjects at unnecessary risk

… hinder efforts to use resulting data to answer the scientific questions being addressed

QbD Implementation: Plan, Do, Check, Act

Build/plan quality into clinical trials from the beginning, focusing on what matters most

PLAN

ACT

Systematically drive remediation and learning

DO

Implement study risk management strategies

CHECK

Monitor leading indicators of quality in the study

CTTI
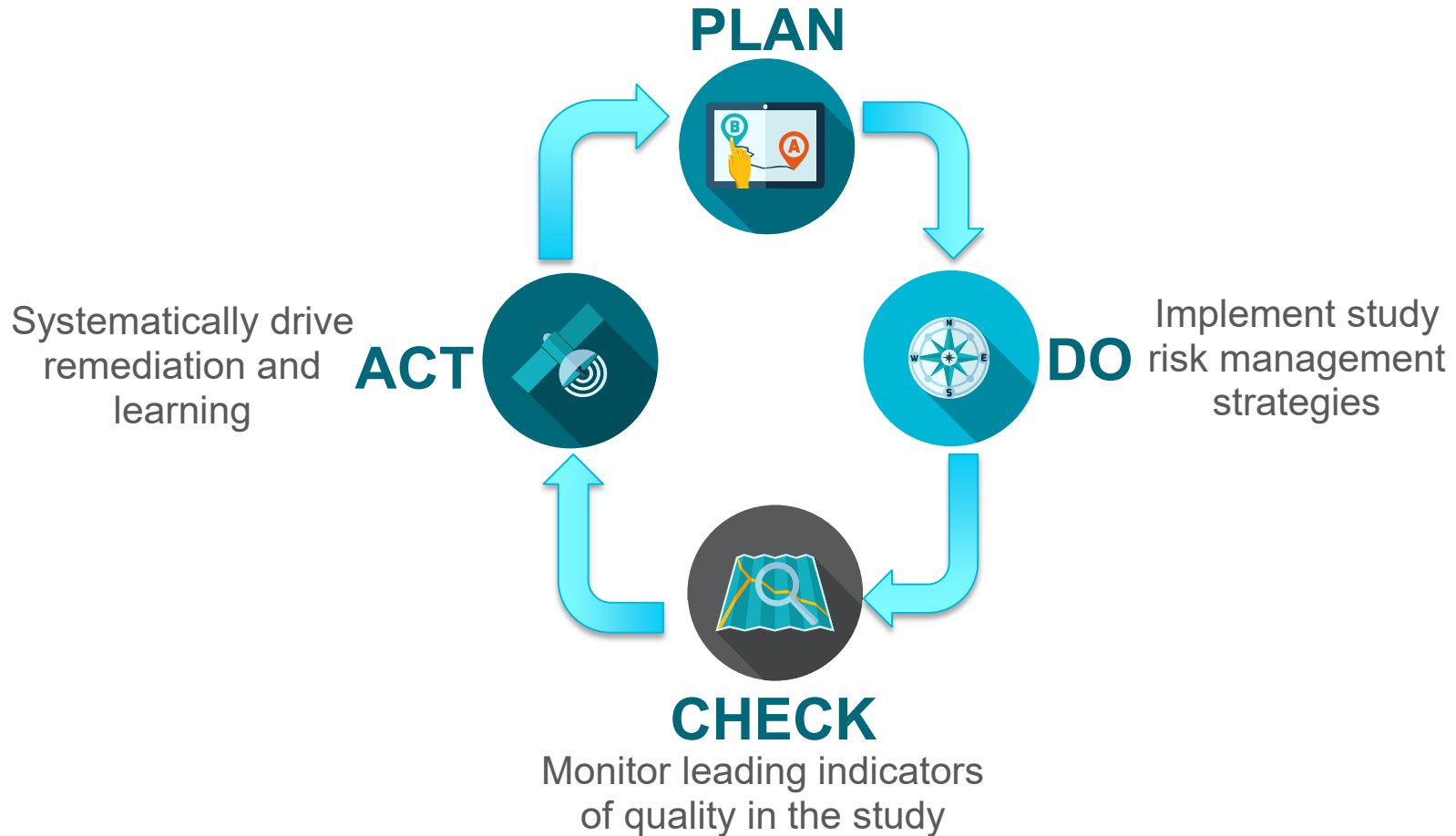
Bringing QbD Into Your Organization

Focus on what matters	▪ "Quality" is defined as the absence of errors that matter ▪ Determine what matters for the specific trial
Develop a quality management plan	▪ Initiate plan in parallel with protocol development ▪ Focus on areas of highest risk for generating errors that matter
Assess performance in important parameters	▪ Prospectively measure error rates of important parameters ▪ Tailor the monitoring approach (e.g., site visits, central, statistical) to the trial design and key quality objectives
Improve training and procedures	▪ Base on measured parameters
Report findings of quality management approach	▪ Include issues found, actions taken, impact on analysis, and interpretation of results ▪ Incorporate into regulatory submissions and publications

CTTI

Use the QbD Toolkit

http://www.ctti-clinicaltrials.org/toolkit/QbD