## What Is Quality by Design?



### **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



### **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 ...

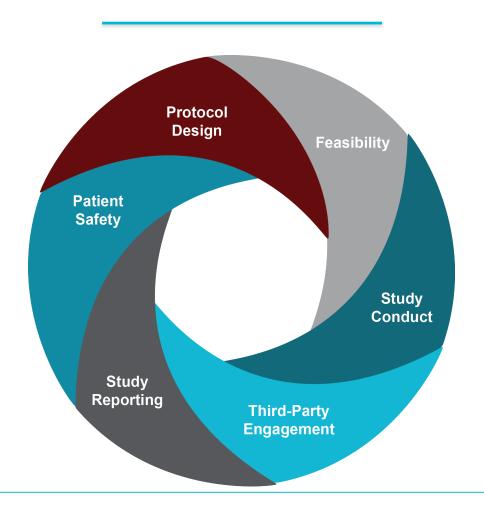
Protect patients during the trial

Obtain reliable results and meaningful information from the trial



### QbD Step 1

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





### QbD Step 2

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





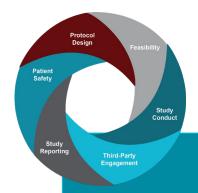
### QbD Step 3

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





# **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





### **Bringing QbD Into Your Organization**

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

Report findings of quality management approach

- interpretation of results
- Incorporate into regulatory submissions and publications



#### **Use the QbD Toolkit**

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



LOGIN

SEARCH

Here to identify and promote practices that will increase the quality and efficiency of clinical trials.

WHO WE ARE

WHAT WE DO

BRIEFING ROOM

TAKE ACTION

CONTACT US







#### QBD TOOLKIT

- Learn About QbD
- Teach Others About QbD

#### RESOURCES

>Adopt QbD

- >Principles Document (pdf) >CTTI QbD Recommendations (pdf)
- >QbD Video Collection
- >Past CTTI QbD Workshops >QbD Project Page



Contact us for questions or comments on the QbD Toolkit

#### Learn About QbD

Teach QbD

Adopt QdD

#### QbD (Quality By Design) Toolkit

This Quality by Design Toolkit is a compilation of documents, templates, guidelines, and videos that will help you put QbD into practice within in your organization. Whether you are first learning about QbD, (Learn About QbD), want to disseminate these concepts within your organization (Teach Others About QbD), or are ready to implement QbD into your clinical trial (Adopt QbD), this Toolkit has resources for you. Refer back to the Toolkit often and find new resources to support you in translating QbD from principles to practice.



#### What is this QbD Toolkit?

Mark Behm from Astra Zeneca describes the QbD Toolkit and how you and your organization can use it to learn about and implement QbD.



#### Why is QbD important for patients?

Nancy Roach from Fight Colorectal Cancer shares the patient perspective on the importance of QbD.

