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

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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.
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

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

**DO**
- Implement study risk management strategies

**CHECK**
- Monitor leading indicators of quality in the study

**ACT**
- Systematically drive remediation and learning

Implement study risk management strategies
### 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 |
Use the QbD Toolkit

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

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 your organization. Whether you are just 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 Rehm 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 Reash from Fight Colorectal Cancer shares the patient perspective on the importance of QbD.