

QbD Launch Studio

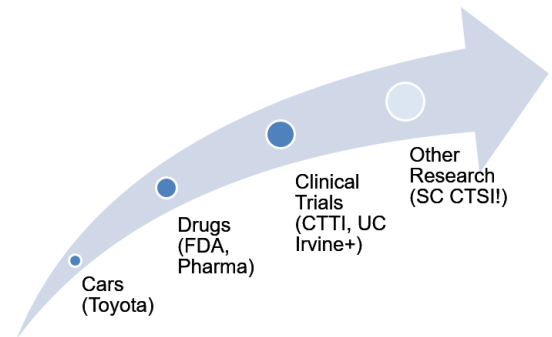
Date:

Study Title:

Meeting Attendees:

Introduction

The SC CTSI is launching a new program to increase the success rate of our funded studies using a quality framework called Quality by Design (QbD). The framework defines quality as the absence of errors that impact the safety of trial participants or the credibility of the trial results. Potential errors are identified at the study design stage with input from a wide range of experts and stakeholders. Risks are closely monitored and addressed throughout the conduct of the study.



Goals

Develop risk mitigation plans; Identify other risks not previously identified by study team; Develop project plan

Agenda

1. PI presents protocol and known risks
2. Study Team and Launch Team, in collaboration:
 - a. Walk through Principles Document to identify additional risks
 - b. Select top 3-5 risks that may impact quality
 - c. Develop mitigation plans
 - d. Develop project plan w/ immediate action items, e.g., recruitment materials
 - e. Identify Project Oversight Team
3. Next Steps
 - a. Set up project plan in SC CTSI project management tool
 - b. Check in with Project Oversight Team on a monthly basis (and as needed)