

Case studies

- * 3 case studies
- * 2 working groups / case study

- * Cardiology outcomes trial
 - * WG1 and WG4
- * Oncology trial
 - * WG2 and WG5
- * Mental health
 - * WG3 and WG6

Day 1: Identify Top “Critical to Quality Factors”

- * Apply QbD principles to hypothetical protocol
- * Identify “Critical to Quality Factors”
- * Rank importance (H/M/L)
- * From “High” importance, select top 3
- * Reporting back:
 - * How were factors approached/selected?
 - * What are the challenges in adopting the principles?
 - * What are the obstacles?

Day 2: Quality Risk Management

- * Consider top “Critical to Quality Factors”
- * What proactive steps can be taken to avoid problems?
- * What ongoing checks can be performed to detect problems?
- * What level of error will trigger corrective actions?
- * How will corrective actions be formulated?
- * How will the impact of any corrective actions be assessed?
- * How will lessons be learned for the future?

Reflection and identification of next steps

- * Review and reflection (what worked, what didn't)
 - * Principles document
 - * Working group approach
 - * Disseminating training within organizations
- * Identify need for further training materials and approaches
- * Identify external barriers to widespread adoption of QbD approach
 - * Who needs to be convinced and how would this best be achieved?