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?