Clinical Trials Transformation Initiative (CTTI)

Pamela Tenaerts, MD, MBA
Executive Director, CTTI
A public private partnership co-founded by Duke and FDA in late 2007

All stakeholders involved

To identify and promote practices that will increase the quality and efficiency of clinical trials
AntiBacterial Drug Development (ABDD)

HAP/VAP pilot study:
Innovative design for HAP/VAP protocol/concept paper:
specifically for issues that are problematic
HAP/VAP Team Leads

Academic:
- Vance Fowler (Duke)
- Brad Spellberg (UCLA)

Industry:
- Gary Noel (AZ)
- Charles Knirsch (Pfizer)
- David Friedland (Cerexa)

FDA
- Rose Tiernan (OMP)
- Jonas Santiago (OAP)
QbD Team leads
- Martin Landray (CTSU Oxford)
- Ann Meeker O’Connell (FDA-GCP)
- Mark Behm (AZ)

QbD Key facilitators
- Sabrina Comic-Savic (The Medicines Co)
- David Rodin (Pfizer)
Handouts at each seat

CTTI representative:
  • Kunal Merchant, PhD
  • Kimberley Smith
  • Joy Adams

Restrooms and document center located in foyer

Wireless internet provided, for access code see handout

Phone conferencing in progress (please mute cell phones)

Refreshments located outside in hall

Working lunch:
  • Brief break before/after lunch
  • Prepare/remove plate
  • return for continued discussion
“Because of the broad array of engaged stakeholders, CTTI is in a unique position to drive major changes in the clinical trial system in the midst of massive global reforms.”

Rachel Sherman, M.D.,
Director for the Office of Medical Policy at the FDA’s CDER
Co-chair of the CTTI Executive Committee.