

Clinical Trials Transformation Initiative (CTTI)

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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)

Housekeeping

- 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

Why CTTI Works

“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.*