

Good Statistical Practice

Good Clinical Practice for Clinical Trials Statisticians

Prof Deborah Stocken for UKCRC CTU Statistics Group

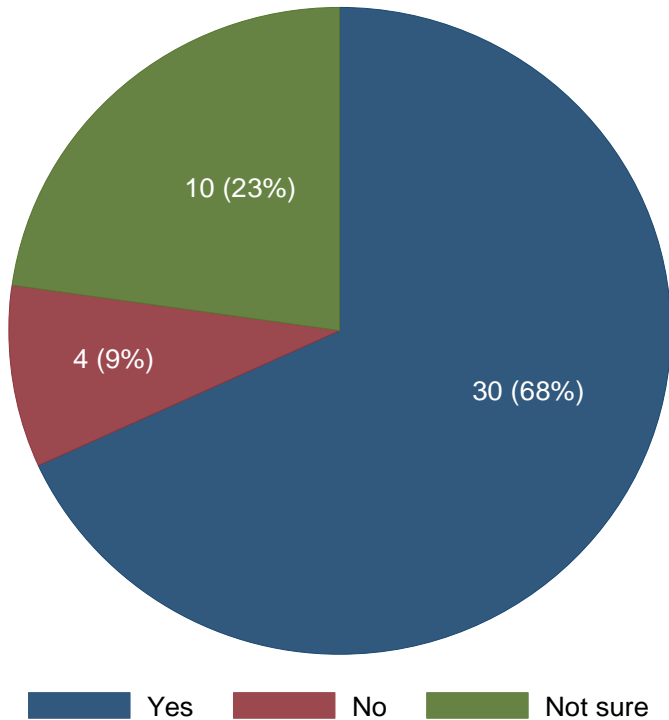
Background

- GCP is an international quality standard applied to all stages of clinical trials
- All trials staff must have training in GCP
- HRA training requirements:
 - “training should be appropriate and proportionate to the type of research undertaken”
 - “researchers are expected to maintain an awareness of current standards”
 - “HRA urges consideration of appropriate training requirements”
- Need for **appropriate, dedicated** development of Statisticians, providing awareness and knowledge of regulatory and research requirements to conduct and document clinical trial activities at highest level
- GCP training identified by the UKCRC CTU Statistics Group as a high priority

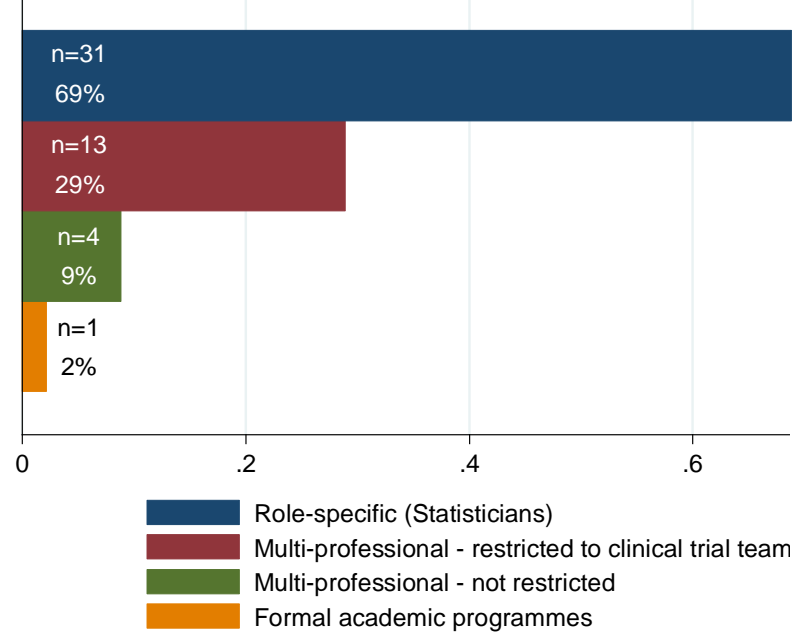
Need for Dedicated Training?



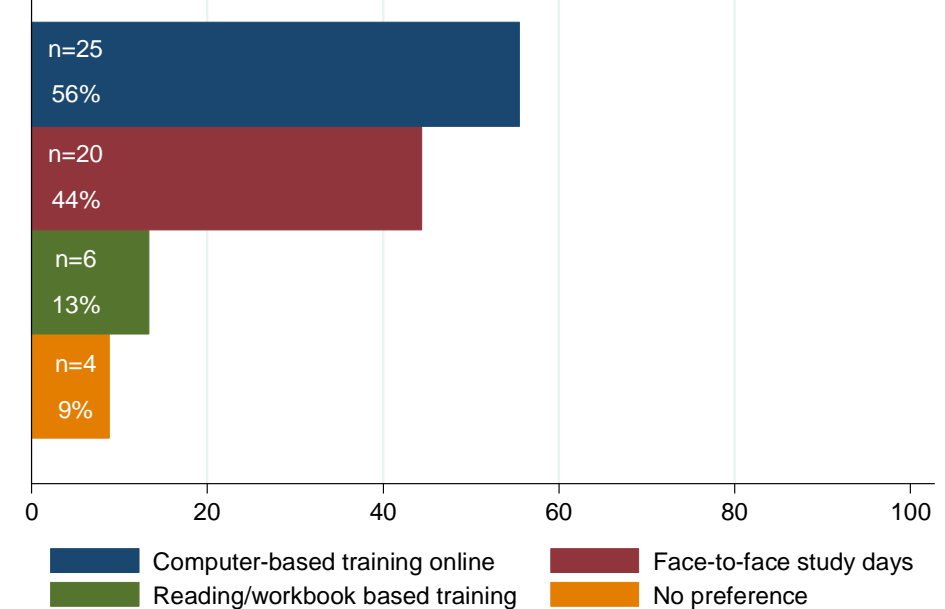
Do you think statisticians need a dedicated GCP training course to be developed specific to their role?



What audience(s) in GCP training would you prefer?



Which form(s) of GCP training would you prefer?



Course Update

- Slide set (v0.7) developed comprising 61 slides (to date)
- Piloted as face to face training in 5 CTUs
- All CTUs provided in-depth slide by slide feedback, positive comments:
 - “people were engaged, and didn't find it too dry”
 - “this is a really valuable tool to add to our training”
 - “something the stats community definitely needs and pleased that this is being taken forward”
 - “really good.... prefer core GCP training be incorporated to save having to do 2 courses”
 - “very positive experience.... a lot more useful than an afternoon spent at standard GCP training”
 - “face-to-face aspects particularly useful.... enabled us to discuss the various aspects in relation to our CTU SOPs, processes and documentation”
- Project supported by NIHR with input from MHRA
- NIHR funding application submitted to complete & disseminate quickly
- Please direct any interest to Deb Stocken, project lead d.d.stocken@leeds.ac.uk