

GCP TRAINING EXPERT MEETING: GOALS

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MOTIVATION FOR THIS PROJECT

- ◆ Clinical trial sponsors all aspire to document that the conduct of their trials follows “Good Clinical Practice”
- ◆ Many ways to try and ensure GCP
 - Clearly written protocol
 - Detailed Manual of Operations
 - Training of investigators and research staff
 - Regular monitoring to assess trial conduct

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MOTIVATION FOR THIS PROJECT

- ◆ Good intentions, unforeseen consequences
 - Many sponsors require their own GCP training
 - Investigators and investigator groups who participate in many trials may be required to undergo multiple training programs every year
 - Much/most material in these programs overlap, as they are based largely on the GCP guidance developed by the International Conference on Harmonization and adopted by the U.S. FDA and other regulatory agencies
 - Diminishing returns from multiple training on same material

CTTI IS ABOUT IMPROVING EFFICIENCY

- ◆ It is not efficient—and not necessary—for investigators and their staff to undergo same training every few months
- ◆ Would be more efficient to have universally and reciprocally accepted content and frequency of GCP training
- ◆ The GCP initiative is intended to move us toward that goal

SPECIFIC MEETING GOALS

- ◆ Seek consensus on
 - the key elements of *GCP* training
 - The frequency and format of such training
 - The demonstration of competency
- ◆ that should be required to conduct clinical studies in the US

THANK YOU!