CLINICAL TRIALS TRANSFORMATION INITIATIVE

Integration of GCP Training into Clinical Research

A Sponsor's Perspective

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Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.

Integrating GCP Training ….. a Journey

Driver for Change: Standard Content & Delivery

2009 – 2011 Context:

- Regulatory observations
  - Variation of content/delivery and inconsistent documentation of training due to lack of standardized GCP training
- Industry benchmarking conclusions
  - Non-standard Investigator GCP training approach across Pharma
  - Web-based training the preferred method for learning

Actions Taken and Results:

- All Principal and Sub-Investigators required to attend one-hour Web based GCP course *(based on ICH-GCP 6 section 4: Investigator Responsibilities)*
  - Centralized documentation and monitoring of training completion
  - Testing component to provide documentation of investigator GCP knowledge
- As of Jan 2014, **43,055 investigators globally** (**16,682 in the USA**) have documented their GCP knowledge via the Pfizer GCP Training Program

Driver for Change: Multiple GCP Training requirements

Equivalence program

- Allows investigators to take a Pfizer approved equivalent GCP training program
- Reduces the burden experienced by investigators during study start-up
- Equivalence program ensures:
  - ICH-GCP Investigator Responsibilities adequately covered
  - Investigator knowledge documentation via testing component
  - Well controlled and documented GCP training program provided by multiple sources
- **4,648 investigators** credited with GCP training through **29 approved equivalent courses.**
  - Equivalence program adds administrative complexity

Further Integration

- Protocol specific training, IVRS, and EDC training delivered/documented through the same web-based platform to introduce more efficiencies for Site and Study teams

Driver for Change: Cross-Sponsor Mutual Training Recognition

Pfizer a founding member of TransCelerate Biopharma, Inc.

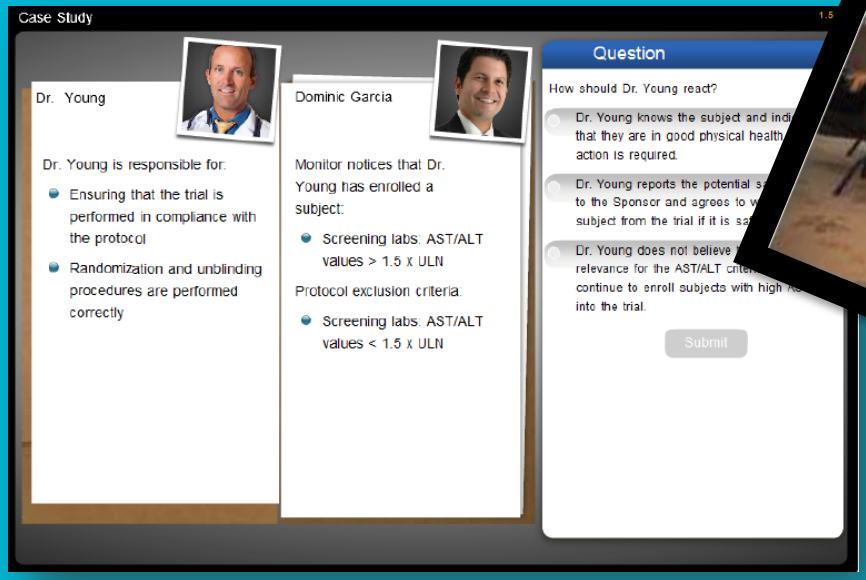
Non-profit organization working to increase quality in clinical trials and improve patient safety.

- Investigator GCP training minimum criteria identified by the Site Qualification and Training workstream.
- Program expanded from recognition of member companies GCP training to include GCP training from vendor organizations
- Every investigator receives a TransCelerate certificate after completing the Pfizer GCP training course
  - Since June 28, 2013, **6,990 investigators** have received Pfizer TransCelerate certificates recognized by many other biopharma companies.
  - **9 of 10 TransCelerate member companies** providing investigator GCP training include a testing component in their course.

Further Information: www.TransCelerateBiopharmainc.com

Driver for Change: One size does not fit all

In addition to the GCP Web based training, Pfizer provides a 2 day instructor-led Investigator Training Program (iTP) for investigators needing a more comprehensive introduction to clinical trials and GCP.



Scenario-based case study from GCP course

2-Day iTP Program

Integrating GCP Training….. a Journey

- Pharma has made great progress over the last 4 years
- GCP training is not a one size fits all
- Going forward –desire to make GCP training as practical as possible so it improves investigator's execution of the study in compliance with GCP

THANK YOU

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