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# 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.

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# 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/documentated 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](http://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.

Case Study 1.5

**Dr. Young**

Dr. Young is responsible for:

- Ensuring that the trial is performed in compliance with the protocol
- Randomization and unblinding procedures are performed correctly

**Dominic Garcia**

Monitor notices that Dr. Young has enrolled a subject:

- Screening labs: AST/ALT values > 1.5 x ULN

Protocol exclusion criteria:

- Screening labs: AST/ALT values < 1.5 x ULN

**Question**

How should Dr. Young react?

- Dr. Young knows the subject and indicates that they are in good physical health. No action is required.
- Dr. Young reports the potential safety concern to the Sponsor and agrees to withdraw the subject from the trial if it is safe to do so.
- Dr. Young does not believe the potential safety concern is relevant for the AST/ALT criteria. He continues to enroll subjects with high AST/ALT values into the trial.

Submit



2-Day iTP Program

Scenario-based case study from GCP course

# 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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