Investigator Training
Site Perspective
CRO/Vendor Perspective

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"…I think we need to up our standards. I think any physician, any doctor who runs a clinical trial should be certified, should be trained."

David Kessler, MD

Former FDA Commissioner

'The Hansen Files' Fact Finder: Drug Trials

March 4, 2012

Why do physicians need training?

- Percentage of naïve investigators, who conduct only one trial per year, has increased to 77% of the global investigator pool.*

- Turnover rate for investigators in both US (43%) and Europe (55.1%) is very high- this prevents investigators from developing strong infrastructure.*

- Human subject protection and data quality are more likely to suffer with naïve sites

*CenterWatch January 2012

Why do physicians need training?

Regulations and Guidance

- Investigator Responsibilities:
  - Section B “Investigators are responsible for protecting the rights, safety, and welfare of subjects during the clinical trial (21 CFR 312.60 & 812.100).
  - The Investigator is responsible for conducting studies in accordance with the protocol (21CFR 312.60, Form FDA 1572, 21 CFR 812.43 & 812.100)
  - Investigators commit themselves to conduct or supervise the study and those people who have been delegated study related tasks (21 CFR Part 812).
  - Investigators are also to ensure the staff is aware of regulatory requirements involving the conduct of clinical trials. This also applies to staff not in his/her direct employ during the study.

Why do physicians need training

ICH Guidelines

- 4.1.1 The investigator(s) should be qualified by education, training, and experience ….. should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date CV and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).
- 4.1.2 The investigator should be thoroughly familiar with the appropriate use of the IP, as described in the protocol(s), in the current IB, …
- 4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements

Available Training

- **The CITI Course in the Protection of Human Research Subjects**
  www.citiprogram.org.
  - Human Subject Protection
  - Conflicts of Interest
  - GCP/ ICH
  - HIPAA and Research Privacy

- **Quintiles GCP Training course:**

  Introduction to Clinical Drug Development Process: ICH/FDA GCP for Clinical Trial Sites

  This online educational program contains six (6) one-hour modules designed for clinical and research staff. This educational program is accredited for five (5) hours of Category 1 CME credit or six (6) contact hours (1 per module) of CEU credit.

- **OHRP Training Available:**
  - **Human Subject Assurance Training**

  http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp

  - **Training Videos**

  http://www.hhs.gov/ohrp/education/training/indeex.html

  Videotape Series: Protecting Human Subjects – consists of 3 videotapes for researchers, institutional officials, students, investigators, IRB members, etc.

- **FDA's Clinical Investigator Training Course**

  Course videos, slides & transcripts on-line at:

  http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/SpotlightonCPIProjects/ucm236523.htm

- **NIH Required Education**:

  Policy: Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. This training can be accessed on the web site of the NIH Office of Human Subjects Research at http://ohsr.od.nih.gov/

Site Training

- CITI

  This the program most widely used by research sites; both private sites and public institutions. Widely accepted by sponsors & IRBs, universities, hospital systems.

- Sponsor Training

  Pfizer & BMS have on-line training with certificated printed for documentation

- Investigator meetings

  GCP done at meetings with documentation

- Site specific training

Investigator Knowledge and Preparedness Study

- Conducted by Harvard Medical School with a grant from Pfizer in association with the Association of Clinical Research Professionals (ACRP). PI: Greg Koski, PhD, MD

- The goal of this study is to objectively assess the current state of knowledge possessed by active clinical investigators in various settings. The study will use an established professional certification examination, the Certified Physician Investigator (CPI) exam offered by the ACRP, to measure how well prepared investigators are to fulfill their responsibilities. The examination covers all aspects of what every principal investigator conducting a clinical trial under the oversight of the Food and Drug Administration or other competent authority should know according to accepted Good Clinical Practice guidelines

EUROPEAN MEDICINES AGENCY

"Training of investigator insufficient, investigator is not familiar with investigational medicinal product and its safety profile"

5th Workshop SMEs 28May2010 Katalina Mettke The BfArM is a Federal Institute within the portfolio of the Federal Ministry of Health (BMG)

Investigator Training
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Investigator

Investigator Site Selection

- Selection of Investigator based on knowledge and experience in therapeutic area
- Investigator and site training often major focus during pre-study site qualification visit
- Review of CVs and training records

Protocol Specific Training

- Site staff listed on Delegation of Authority must have adequate training
  - Protocol specific training
  - GCP training
  - Study specific procedures
- Study specific training logs and/or forms
  - Site Initiation Visit training
  - Software training documents and certificates

Protocol Specific Training

- Electronic data capture systems
  - eCRF
  - Physiologic data capture – ECGs, Spirometry devices, scales, stadiometers
  - Subject diary systems
- Training provided by vendor or CRO
  - Tutorials
  - Certificates
- All users required to be trained

Protocol Specific Training

- Training may be completed at the IM
- On-site tutorials or training sessions (by the vendor or monitor)
- Remote access training such as Web Cast
- Study Procedure Manual
    - Detailed instructions on how to use hardware and software

Protocol Specific Training

- Successful completion of tutorials or training
  - Ensures quality data
  - Site users will be able to properly train subjects
- Vendors provide on-going support during a study
  - On-site or remote training

QUESTIONS ??

How do you get investigator buy-in if it's not required?

QUESTIONS ??

Should sponsors pay the investigators for the time to do the training?

QUESTIONS ??

Could research training be incorporated into medical education or as optional course work?

Contact information

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