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**Differential Training by
Job Function**

ACRP Job Analysis Results

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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.

ACRP Job Analysis Survey

- ▶ **Job analysis – designed to identify knowledge, skills and abilities (KSAs) required to perform a job safely and effectively (*aka - competency*)**
 - ▶ Linked to actual job roles and responsibilities + knowledge required to carry out duties
- ▶ **First-ever international job analysis for clinical research professionals**
 - ▶ Completed December 2010
 - ▶ Sent to 60,000+ clinical research professionals
 - ▶ Nearly 4,000 responses received from every US state + 66 nations
 - ▶ Respondents included those ACRP certified and those not
 - ▶ Same survey sent to everyone

Job Analysis Survey - Content

- ▶ **Survey included 131 task statements**
 - ▶ Respondents asked to rate each statement on two scales
 - ▶ **Importance to competent performance**
 - ▶ **Perform or manage the task?**

- ▶ **Survey included 86 knowledge statements**
 - ▶ Respondents asked to rate each knowledge statement on two scales:
 - ▶ **Importance for competent performance**
 - ▶ **At what cognitive level is knowledge needed?**

Job Analysis Results

- ▶ **Responses provide level of emphasis**
 - ▶ Tasks rated more important have greater content coverage
 - ▶ Cognitive level ratings are directly tied to the type of questions on exam about a topic (recall item vs. application vs. analysis)
- ▶ **Results analyzed across:**
 - ▶ Declared job roles (CRC, CRA, PI)
 - ▶ Practice settings
 - ▶ Type of trials conducted (drug, device, biologic, etc.)
- ▶ **Outcomes**
 - ▶ Test specifications for each job role emphasizing knowledge and skill areas pertinent to the role
 - ▶ Identifies competency larger than just GCP

Job Analysis Results: Differential Weighting of Content By Job Role = Test Specifications

	CCRC	CCRA	CPI
Investigational Product Management	7%	10%	5%
Protocol	13%	20%	10%
Safety	16%	25%	25%
Trial Management	58%	30%	50%
Trial Oversight	6%	15%	10%

Content Development – KSAs Differ Depending on Role

- ▶ **Content developed by experts in each job role**
 - ▶ Tied directly back to test specifications in terms of:
 - ▶ emphasis (more important = more questions)
 - ▶ cognitive level (knowledge used at a basic level = recall questions; mastery level = analysis questions)
- ▶ **Written from perspective of requirements for job function**
 - ▶ Same knowledge statements covered across all three roles but with implications for job duties considered
- ▶ **All items referenced to ICH Guidelines E2A, E6, E8, E9 to provide defensibility**

Protocol Domain

- ▶ **9 Knowledge statements that are the same**
 - ▶ Protocol development
 - ▶ Protocol submission and approval procedures
 - ▶ Clinical trial phase
 - ▶ Study design characteristics (e.g., double-blind, crossover, randomized)
 - ▶ Study objective
 - ▶ Description of procedures
 - ▶ Amendment submission and approval procedures
 - ▶ Inclusion/exclusion criteria
 - ▶ Statistical plan

Protocol Domain

- ▶ **Coordinators (13%) – 9 task statements that focus on:**
 - ▶ Evaluating protocol for feasibility
 - ▶ Evaluating congruence of data collection tools with protocol
 - ▶ Verifying eligibility of potential pool of trial subjects
- ▶ **Monitors (20%) – 13 task statements that focus on:**
 - ▶ Identifying study objective and design
 - ▶ Developing the protocol (inclusion/exclusion criteria, procedures, schedule of events, safety and efficacy parameters)
 - ▶ Evaluating protocol for feasibility
- ▶ **Investigators (10%) – 13 task statements that focus on:**
 - ▶ Identifying study objective and design
 - ▶ Evaluating protocol for scientific soundness and feasibility
 - ▶ Complying with the protocol (inclusion/exclusion criteria, procedures, schedule of events, safety and efficacy parameters)

Trial Management Domain

- ▶ **Coordinators (58%) – task statements that focus on:**
 - ▶ Developing recruitment scheduling, screening and retention strategies and plans
 - ▶ Maintaining source documents, Essential documents and trial master files
 - ▶ Participating in the informed consent process
 - ▶ Collecting, recording and reporting accurate and verifiable data
- ▶ **Monitors (30%) – task statements that focus on:**
 - ▶ Developing study documents (CRFs, ICFs, tracking tools, monitoring plans and guidelines)
 - ▶ Ensuring timely review of study data
 - ▶ Performing monitoring duties (on-site/centralized/remote)
 - ▶ Facilitating site-related budgets, contracts, training, queries and issues
- ▶ **Investigators (50%)– task statements that focus on:**
 - ▶ Ensuring appropriate equipment, staff qualifications and other resources
 - ▶ Participating in the informed consent process
 - ▶ Conducting subject visits in compliance with the protocol
 - ▶ Collecting, recording and reporting accurate and verifiable data

Consider the Goal:

- ▶ **The goal of GCP is to protect the rights and safety of study participants, and the quality of study results.**
- ▶ Tick a regulatory box *OR*
- ▶ Provide evidence of competency in the knowledge and skills required to conduct safe and ethical trials that provide reliable, scientific data

Resources

- ▶ **Job specific Detailed Content Outlines available on the ACRP website**
- ▶ **www.acrpnet.org**
 - ▶ Navigate to each program to find specific DCO
 - ▶ Certified Clinical Research Coordinator (CCRC®)
 - ▶ Certified Clinical Research Associate (CCRA®)
 - ▶ Certified Physician Investigator (CPI®)

▶ THANK YOU



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