

Clinical Research Advancement in the Sponsor Organization: Establishing Core Competencies and Performance Assessments



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Agenda

- **Background**
- **Development of Assessments**
- **Results**



Background

- **Generic Job Descriptions**
- **Lack of Global Standard Assessments**
 - **Manager's perception of competency or need improvement areas**
 - **Previous industry or clinical experience**
- **No individual-focused training available**
- **No 1:1 comparison within each job function available**



Goal

- **Establish EU and US standard competency assessments for each job function**
- **Establish global standard training program**
- **Establish individual-based training program**
- **Obtain additional data to support promotion/advancement within the organization**
 - **minimize perception disparity**



Target Audience

- **Clinical Project Coordinators (i.e., CRA Assistants)**
- **CRA 1, 2**
- **Sr. CRA**
- **Associate CPM**
- **CPM**
- **Sr. CPM**



Methods

- **ICH GCP Online Assessment**
- **Practical Application Assessments**
 - **Case studies**
 - **Monitoring issues**
 - **ICF, IRB issues**
 - **Study Drug**
 - **Budgets**



Timing

- **Yearly**
- **Cumulative for the first assessment**
- **Pilot program (completed)**
- **US**
- **EU**



Results

- **Share with individual and manager**
 - **Review data**
 - **Development plan**
 - **Individual-based training**
- **Review overall data to address global training issues**
 - **Develop focused job function training program**



Development of the Competency Assessments

Two-part process:

- 1. Development of Core Competencies**
- 2. Development of Assessments for the Defined Competencies**



The Process for Development of Core Competencies

1. Definition of the areas of competency for each job level (**Consultant**)
2. Confirmation of competency areas (**Sponsor**)
3. Definition of detail for each competency area with each job level (**Consultant**)
4. Approval of core competencies for all job levels (**Sponsor**)



Core Competency Areas

- 1. Drug Device/Biologics Development Knowledge**
- 2. Regulations and Guidelines Knowledge**
- 3. Medical & Scientific Knowledge**
- 4. Information Technology Skills**



Core Competency Areas

5. Verbal Communication & Negotiation

6. Written Communication

7. Clinical Study/Project Management

Activities Before, During and After Subject Enrollment

8. Data Management



Core Competency Areas

9. Budgeting/Resourcing/Financial Management

10. Leadership

11. Problem Solving

12. Teamwork

13. Additional Knowledge Skills and Experience



Key Points About Core Competencies

- **Developed based upon published literature, industry experience and bench-marking.**
- **Some competencies were required at more than one job level.**

Example included at multiple levels:

Clinical Study/Project Management

Activities Before Subject Enrollment

→ **Organizes work and prioritizes according to study timelines**



Example Core Competencies for CRA- 1

1. Drug Device/Biologics Development Knowledge

Understands the key elements of the informed consent form

3. Medical & Scientific Knowledge

Demonstrates the ability to read and interpret medical charts



Example Core Competencies for CRA-1

5. Verbal Communication & Negotiation

Effectively listens and asks questions for clarification

7. Clinical Study/Project Management

Monitors sites when required, based on enrollment, issues, timelines, etc.



Example Core Competencies for CRA-1

10. Leadership

- **Follows up on commitments**
- **Comes to meetings prepared with information and takes responsibility for sites**

11. Problem Solving

- **Understands the nature of the problem and focuses on the facts**



Example Core Competencies for Sr. CPM

1. Drug Device/Biologics Development Knowledge

Has a working knowledge of clinical plans and their critical paths

3. Medical & Scientific Knowledge

Demonstrates awareness of competitor products and developments with respect to their indications and marketing strategies



Example Core Competencies for Sr. CPM

5. Verbal Communication & Negotiation

Negotiates resources and timeline issues at the management level of company business units

8. Data Management

Interacts with management of Data Management/Stats to ensure study database supports an integrated global database for regulatory submissions



Example Core Competencies for Sr. CPM

9. Budgeting/Resourcing/Financial Management

Completes projects within budgeted amount; negotiates for changes

10. Leadership

Defines, contributes to and oversees specific-project level training

12. Teamwork

Effectively handles issues that are often complex, multi-disciplinary & cross-functional

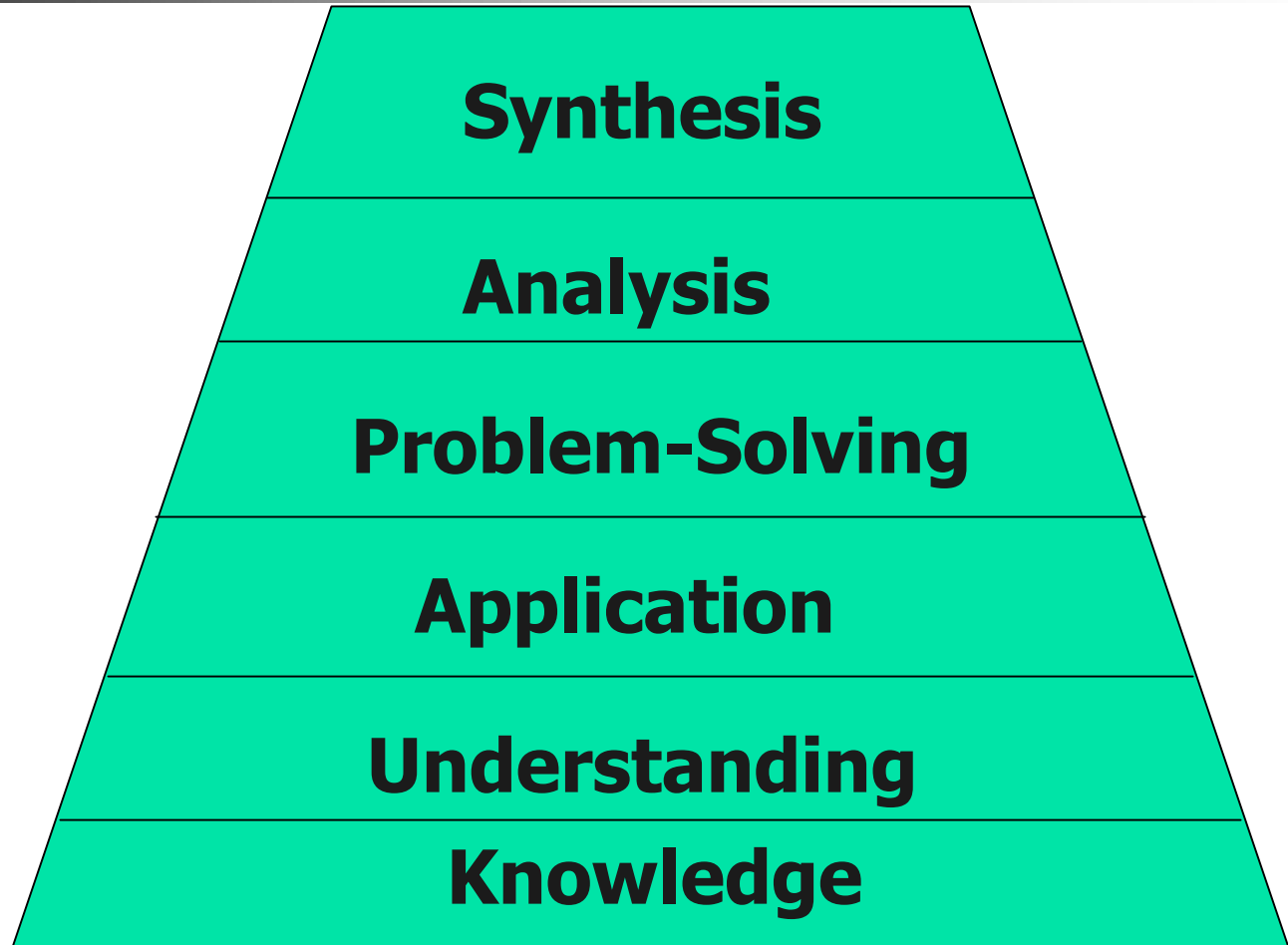


Development of Competency Assessments

Competency Assessments Should:

- **Parallel the expected performance on the job.**
- **Integrate competencies to mimic the actual clinical trial setting.**
- **Evaluate multiple levels of learning, and must evaluate the highest level required for the job.**

Development of competency assessment criteria based on Bloom's Taxonomy





Methods to Assess Competency

Electronic testing for GCP and General Knowledge

- **Developed a pool of questions which randomly appeared during testing with randomly-presented responses for control.**
- **Written problem-solving assessment provided by the manager.**
- **Promotion requires competency demonstration assessment at the next level. (E.g., CRA-1 takes the CRA-2 assessment, prior to promotion)**



Sample Competency Questions: GCP

- **According to FDA regulations, investigators are required to attend a multicenter initiation meeting if one is held. True or False?**



Sample Competency Questions: GCP

- **FDA guidelines require sponsors to inspect case report forms for legibility. True or False?**



Sample Competency Questions: GCP

- **Study monitoring observations of deficiency should be maintained privately at the sponsor and the investigator should be told verbally, to avoid inadvertent incrimination.
True or False?**



Sample Competency Questions: GCP

- **To whom do the FDA's regulations on financial disclosure apply?**
 - **Principal investigators**
 - **Sub-investigators**
 - **Study coordinators not named as sub-investigators**



Sample Competency Questions: GCP

- **The best time to resolve data queries is:**
 - ❑ **Within 30 days of receipt of the data**
 - ❑ **After all subject data has been received and entered from all sites**
 - ❑ **When the statistician has completed the analysis of the data**



Drug Supplies Problem-CPM Level

You are monitoring a study in which patients participate for 9 months. The study has overall delayed enrollment. After 10 months, a decision is made to amend the protocol and modify the inclusion criteria to permit enrollment of additional subjects. The original drug supplies that were shipped to each of your investigators had a shelf life of 15 months.

What information should you provide to the investigators regarding use/non-use of investigational supplies with expired labeling?



Study Closure-CPM Level

- **You are closing a multicenter study with 50 centers. Draft a letter that all team members should send to their investigators regarding financial disclosure regulations**



Informed Consent – CRA-1 Level

- **Review the attached sample informed consent form. Using the following list of elements of informed consent, place the letter corresponding with each element in the left margin adjacent to the text in the sample informed consent form where that element is present.**



Monitoring- CRA-1 Level

Suppose during a monitoring a visit you observed a medical record entry that a subject called-in reporting a severe headache. The physician on-call was not the investigator, but instructed the subject to take aspirin or ibuprofen and phone back if the problem continued beyond 6 hours. The protocol exclusion criteria stated that subjects may not consume salicylates during the study.

What action(s) should you take with the investigator/study coordinator?

Write the text that should appear in your monitoring report:



Adverse Events- All levels

Write the FDA's definition of "unexpected" when referring to an adverse event:

What is the ICH definition of a life-threatening adverse drug experience?



Drug Accountability CRA -1 Level

Using the following data, complete the final Sample Drug Accountability Calculation that follows the data.

The Sponsor shipped drug for 25 subjects, consisting of 100 bottles of test drug, containing 100 tablets, each on March 13. Each subject receives 4 bottles of test drug. Patient consumption information for Dr. Smith's study is as follows...

The sponsor received the following returned materials from the investigator on Dec. 17.



Monitoring-Sr. CRA Level

You are accompanying a new CRA during a monitoring a visit. The CRA observes a witness signature on the original informed consent form for subject # 303. During the study, the informed consent form was amended, the subject signed the amended informed consent form, prior to implementation of the amendment. However, no witness signature was observed on the amended consent form.

Write an explanation of what action(s) you should take as a Sr. CRA mentor, and what actions you should direct the new CRA to make.



Annual Reports-Sr. CRA Level

You are assigned to coordinate, collect and assemble the IND annual report data for an ongoing multicenter study of 50 sites. There are 5 CRAs monitoring the program, 3 from a CRO and 2 from the sponsor.

Write a memo to the CRAs that describes the requirements for this report and the actions the CRAs should take.



Summary of Preparing Competency Assessments

- 1. Define core competencies for each job level.**
- 2. Develop questions that integrate all areas of competency.**



Pilot Program

- **Sample Size**
 - **2 CPCs, 1 CRA, 2 ACPMs, 1 CPM**
- **Level of acceptance in pilot group**
 - **High**
- **Results**
 - **ICH-GCP Guidelines and FDA Regulations (electronic assessment)**
 - **Competency > 88% in all groups**



Pilot Program

- **Practical Application Assessments**
 - **Clear indication of growth areas for each participant**
 - **Inconsistency between job functions on how tasks are completed**
 - **Greatest inconsistency in the:**
 - **CPC group**
 - **Junior participant in same job function**



Next Steps

- **Individual Development Plans**
- **Develop Job Function Standard Training Program**
- **Pilot Program in EU**



Thank you

- **Slides available at:**
www.raninstitute.com

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