

More than a Monitor: Developing Advanced CRA Skills



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The CRA's job is to help an
investigative site properly
conduct a clinical trial for a
sponsor.



Experienced CRAs
Solve Problems,
They Do Not Create
Problems.



Quick Review of Basic CRA Skills

GCP Knowledge

- 21 CFR 50 (Consent)
- 21 CFR 54 (Financial disclosure)
- 21 CFR 56 (IRB)
- 21 CFR 312 (IND)
- 21 CFR 812 (Devices)
- Guidelines (ICH and others)



Quick Review of Basic CRA Skills

- Source document review
- Adverse event management
- Regulatory document review
- Investigational supply review
- Informed consent/IRB issues
- Investigative site compliance
- Investigative site issue resolution

Advanced CRA Skills

1. Applying clinical and medical logic to monitoring
2. Developing rapport and effective relationships with investigative staff
3. Applying education and training techniques to improve site performance



Applying Clinical and Medical Logic to Monitoring

- You need knowledge
- Knowledge categories:
 - Basic pharmacology & pharmacokinetics
 - Classes and uses and drugs
 - Medical conditions and language
- Integrate and apply your knowledge during the data review process



Exercise in Applying Clinical and Medical Logic to Monitoring

- Work with two other people
- Generate a list of 3 specific examples that apply clinical or medical knowledge in study monitoring.



Developing **Rapport
and an
Effective Relationship
With Investigative Staff**



Why doesn't the site
do what they are
supposed to do?



Solutions for Getting a Site To Do What They are Supposed To Do:

1. Understand the business relationship.
2. The sponsor (CRA) must train, explain and communicate **WHAT** should be done and **WHY**.
3. Treat people right.
4. Be the Solution, Not the Problem.



Applying Education and Training Techniques to Improve Site Performance



Training Times During a Study

- **At the evaluation visit**
- **At the initiation visit**
- **During every monitoring visit**



**Use monitoring
observations as the basis
for continual site learning
and improvement.**



A Learning Model

1. Introduce the topic.
2. Describe requirements, and demonstrate.
3. Allow learner to practice.
4. Give constructive feedback.
5. Assure learner demonstrates the correct practice.
6. Give positive feedback.
7. Continue to monitor for correct practice.



Tips for Giving Constructive Feedback

1. Ask the recipient if they would be receptive to some feedback.
2. Start with a positive statement of something they do well.
3. State the feedback in a positive statement.
4. Focus on the action, not the person.
5. Close with a positive statement.

Constructive Feedback Exercise

- **3 roles: CRA, CRC/Investigator, Observer**
- **Scenario:**

Your study requires an investigator reason code for all out of range lab values. Monitoring finds the codes not recorded. CRAs job is to give CRC/Investigator constructive feedback.



Make Your Life as a CRA Easier

- **Work smarter, not harder.**
- **Take full responsibility for communication with the site and resolution of issues.**
- **Continually improve.**



Be The Solution!

*Presentation slides available on
The RAN Institute website
www.raninstitute.com*

