Monitoring the CRA
Achieving High Quality Clinical Research Seminar Series
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Introduction

• Agenda
  • Definition of a CRA
  • What types of visits are CRA’s responsible for?
  • What else do CRA’s do?
  • What can you do to help maximize the relationship with your CRA?
  • Tips for Study Coordinators
  • What do study teams expect from CRA’s
  • Summary
  • Time for questions
Disclaimers

- The contents of this presentation are our own and do not represent the opinions or advice of our current employers or clients.

- The information regarding the FDA CFR contained in this presentation was obtained from publicly available sources. Our interpretation of this information is also ours.
Nicolás Samper, MS, CCRA

- **Education**
  - BS in Biology - Rochester Institute of Technology (RIT)
  - Certificate in Clinical Trials Management - Boston University (BU)
  - MS in Project Management - BU

- **Work Experience**
  - Quintiles – Clinical Project Manager
  - Amgen - CRA
  - Bausch and Lomb
  - Biogen Idec
  - Genentech
  - Adjunct Professor in RIT’s Clinical Research Management program

- **Certification**
  - Certified Clinical Research Associate (CCRA) by ACRP

- **Why do I choose to work in Clinical Research?**
FDA Definitions

- TITLE 21--FOOD AND DRUGS,
- CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES,
- SUBCHAPTER D--DRUGS FOR HUMAN USE
- PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION,
- Subpart A--General Provisions,
- Sec. 312.3 Definitions and interpretations.
  - Clinical investigation
  - CRO
  - FDA
  - IND
  - IEC
  - IRB
  - Investigational new drug
  - Investigator
  - Marketing application
  - Sponsor
  - Sponsor Investigator
  - Subject
FDA requirements for selecting monitors

- TITLE 21--FOOD AND DRUGS
- CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES
- SUBCHAPTER D--DRUGS FOR HUMAN USE
- PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION
- Subpart D--Responsibilities of Sponsors and Investigators
- Sec. 312.53 Selecting investigators and monitors.
  - 23 lines of requirements for investigator
  - 1 sentence describing what a sponsor needs to select a monitor
    - (d)A sponsor shall select a monitor qualified by training and experience to monitor the progress of the investigation.
Definition of a CRA(Con’t)

- The industry has a broad definition
  - CRA(Clinical Research Associate)
  - CSM(Clinical Site Manager)
  - Study Monitor
- Every sponsor has different expectations
- Help sites navigate the protocol, enroll the correct patients, ensure patient safety, maintain data quality, retain patients, and follow GCP guidelines.
Types of CRA’s

- Who employs the CRA?
  - Sponsor CRA
  - CRO CRA
  - University CRA
  - Independent Contractor CRA
- Where are they based?
  - Home based or office based
- How are they aligned?
  - Therapeutic alignment vs Regional alignment
- What is their territory
  - Local vs. Regional vs. Country vs. International
- What are they responsible for?
  - Different responsibilities and authority level based on sponsor
  - But All should be able to access protocol related information for you.
Becky Gavitt Introduction

• Education
  • BSN from Jacksonville University
  • Certificate in Clinical Data Mgmt.

• Work Experience
  • PRA/RPS – Sr Site Manager
  • RGH- study coordinator Lipson Cancer Center
  • Quintiles
  • Kendle

• Certification
  • Certified Clinical Research Associate (CCRA) by ACRP

• Why do I choose to work in Clinical Research?
• What do I like about being a CRA?
What types of site visits are CRA’s responsible for?

- SEV’s, SQV’s, SSV’s, PSV’s
  - Follow monitoring guidelines set by sponsor
  - Ensure oversight is evident
  - Is patient population available
  - Consistency across sites
- SIV’s
  - Highlight special and unusual procedures/processes
  - Develop a good rapport with your subjects to ensure compliance, maintain retention and maintain trust
What types of site visits are CRA’s responsible for?

- IMV’s, PMV’s
- COV’s
- Other Visits
  - Recruitment Visits
  - Territory Development Visits
  - Remote Monitoring Visits
What else do CRA’s do?

- Manage our own Schedule based on Monitoring Plans
- Travel
- Multiple Protocols/ Multiple Therapeutic Indications
- Data Deadlines
- Audit Responses
- Teleconferences (Protocol related. Manager related)
- Phone Calls
- Training
- Mentoring
- Expense Reports
- Timesheets
- Regional and National Company Meetings
- Investigator Meetings
- Remote Working Pro’s and Con’s
- Buy your own supplies for office and visits
Sue Parsons Introduction

- **Education**
  - BA Biology University of Rochester
- **Work Experience**
  - Parsons Clinical Research Consulting, LLC – Owner/Independent Clinical Research Consultant
  - **Clients Include**
    - CTCC at University of Rochester, Ethicon EndoSurgery and PPI (J&J subsidiaries), BioMarin, Bayhill, Cytokinetics, Sanofi, Progenics, Kos Pharmaceuticals and several CROs
    - Sankyo USA Corporation (Pharma) – CRA/Project Manager
    - Oxford Research Corporation (CRO) – CRA
- **Why do I choose to work in Clinical Research?**
- **What do I like about being a CRA?**
What can you do to help maximize the relationship with your CRA?

- Help them find your location
- Ensure your CRA has scheduled time to meet with you, the pharmacist, the PI and other critical site study staff either during the visit or at the end of the visit to review findings.

What does the CRA expect from their site?

- Updates of any new Safety information (SAE’s, several AE’s)
- PI oversight of AE’s and SAE’s with Clinical Significance review
- Ongoing oversight of AE’s and Con Meds
- Any staff changes
- Any pregnancies
What can you do to help maximize the relationship with your CRA?(Con’t)

- What does the CRA expect from their site?(Con’t)
  - All Relevant Medical Records available
  - Help navigating your EMR
  - A review of your screening procedures and where it’s documented
  - All data entered into CRF or eCRF
  - All queries are closed
  - All study documents filed
  - All IP accounted for and whether it was administered properly (If applicable)
    - Talk to your patients
  - All PI signatures complete with dates
Tips for Study Coordinators

- **How to manage issues with CRA’s**
  - Your CRA needs to follow the Monitoring Plan at all applicable visits
  - Your CRA needs to meet with all appropriate study staff at all applicable visits
  - The faster they can finish their tasks, the less you need to see them
  - You should feel like you can go to your CRA for guidance, and as a reference source.
    - If your CRA can’t answer it, they should be able to escalate it to the sponsor study team. It’s their responsibility.
    - You should not have unanswered questions

- **Demand Timely Communications**
  - Confirmation of their upcoming MV
  - Follow Up findings from MV
  - When is the next MV scheduled for?
  - Has a visit with applicable staff been scheduled?
Tips for Study Coordinators (Con’t)

- How to manage issues with CRA’s (Con’t)
  - You can ask for advice. If you don’t get the answer you need, you should escalate to the Study Manager or CRA Manager.
  - You should feel empowered to ask questions and escalate if needed.
  - You should feel respected by your CRA.
  - If there truly is a personality conflict, you should feel like you can change CRA’s.
  - If it’s a respect or knowledge gap with your CRA, you may need to escalate.
  - If you need something or don’t know, ask. If you find an error in the protocol, let someone know.
  - Learn your CRA’s style of monitoring and working style.
    - Do you prefer to review questions on an ongoing basis, or at the end of the day?
  - Plan ahead and try to anticipate what the CRA will need and ask for.
What do study teams expect?

- Collaboration with sites
- CRA’s will find problems
- CRA’s don’t know all the answers
- CRA’s should not make decisions they’re not informed to make
- Proactive when identifying problems (issues/findings)
- Timely reporting of findings
- Document their findings
- Communicate difficult messages in a respectful manner
- Ask for help
- Polite
- Punctual
- Ability to work with different personalities
- Awareness of the relationship between site and sponsor
Traits we want in a CRA

Reese, Brenda (2011), *The Seven Key Traits of the Great CRO CRA*, Monitor, September, 28-30

- Personal Commitment to high quality data
- Positive, “can do” attitude
- Excellent organizational skills
- Ability to embrace inevitable change
- Desire to stay engaged
- Know-how to prevent personal burnout

- Communication skills
- Independent worker
- Conflict Resolution Skills
- Risk Management
Traits we have in common

- We want respect
- Overworked
- Stressed
- Demanding protocol
- Interest in patient safety
- Protocol compliance is critical
- Pressure to maintain data quality
- Timely data management
- IP management challenges
- Staff turnover pains
- Value open, clear and timely communication
Summary

- We’re on the same team
- Anticipate what your CRA will ask you for
- Don’t take issues personally
- Issues vs. Trends
- Unexpected requests will always pop up
- There will always be queries.
- So collaborate and form a partnership with your CRA to improve your efficiency. Use them as a resource to help you feel more prepared.

“In these times of nursing shortages and high turnover high quality, collaborative partnerships between nursing faculties and the health care sector are seen as a possible solution to optimize clinical learning and therefore graduate preparedness.” BROWN, D., WHITE, J. and LEIBBRANDT, L. (2006),
References

- Reese, Brenda (2011), *The Seven Key Traits of the Great CRO CRA, Monitor, September, 28-30*
Questions?

Thank you for your time!