The Great Resignation, Compliance, and How to Restock the Pond

Health Care Compliance Association ~ Research Compliance Conference
Phoenix, AZ, June, 2023

Cindy Dunn, Consultant, Crescent City Research Consulting LLC
Alexis Shaffer, Sr. Business Development Director, Medix
Wendy Portier, Consultant, Portier & Associates, LLC

The Great ~~Resignation~~ Regret, Compliance, and How to Restock the Pond

Health Care Compliance Association ~ Research Compliance Conference
Phoenix, AZ, June, 2023

Cindy Dunn, Consultant, Crescent City Research Consulting LLC
Alexis Shaffer, Sr. Business Development Director, Medix
Wendy Portier, Consultant, Portier & Associates, LLC

Objectives

- Discuss the critical impact of research staff turnover on research study execution and how to mitigate potential compliance issues

- Describe strategies to attract, retain and motivate research staff to build a successful research program and share lessons learned

- Identify challenges, opportunities and successes when onboarding new staff and managing managing remote workers

Speakers

Cynthia Dunn, RN, BSN, MSN, CCRA, CCRP, CPC
Consultant
P 504.319.6864
cindy@ccresearchconsulting.com

Cynthia (Cindy) Dunn is an experienced and diverse clinical research professional with over 25 years of healthcare experience including: Clinical Research, Clinical Research Compliance, and Oncology Nursing. Having worked as an Oncology Research Coordinator, Interim Director Clinical and Regulatory Operations, Monitor, Project Manager and CRA Manager, Cindy offers valuable insight from both the site and sponsor perspectives of clinical research.

Cindy has consulted with multiple research sites in the following areas: Operations enhancement and Process Improvement, Audits (of Phase I-IV trails, including investigator initiated studies (Good Clinical Practice (GCP)), Inspection Readiness, Gap Analysis; Risk Assessment, Clinical Research Training; Interim Staffing; Due Diligence Assessment and Standard Operating Procedure (SOP) infrastructure. Additionally, she has provided a variety of services to multiple pharmaceutical companies including: Monitoring, Site Management; Clinical Research Associate (CRA) Management, Contract Research Organization (CRO) Oversight, Vendor Management, Project Management, Auditing, Trial Master File (TMF) Management, Training, and Inspection Readiness.

Cindy holds a Master of Science in Nursing in Clinical Research Management from Duke University. She also holds research related certifications from ACRP and SOCRA and has lectured locally, nationally and internationally on various topics related to clinical research.

Speakers

Alexis Shaffer
Senior Business Development Director, National Clinical Research
P 210.551.5361
alexis.shaffer@medixteam.com

Alexis Shaffer has 7 years of experience in talent acquisition within healthcare and life sciences spaces. Alexis is passionate about driving the development of new therapies by partnering with research companies to identify, attract, and retain top talent in the industry. Alexis is currently a Senior Business Development Director at a life sciences recruitment agency. In this role, Alexis serves as a talent acquisition consultant for numerous organizations including Clinical Research Sites, Sponsors, Clinical Trial Organizations, Integrated Research Organizations, Research Service Organizations, and Research Technology companies. Collaborating with a variety of different organizations has provided Alexis with the experience, knowledge, and ability to guide and advise hiring teams on how to best staff and develop research teams.

Speakers

Wendy Portier, MSN, RN, CHC, CHRC, CPC
Consultant
P 504.782.1328
wendy@portierandassociatesllc.com

Wendy Portier has over 25 years of experience in health and managed care including: Health Care Compliance, Research Compliance, Consulting, Clinical Research, Critical Care Nursing, Quality, Utilization Management, Case Management and Disease Management. Having worked on the provider, researcher, payer and sponsor sides, Wendy has a unique perspective and extensive knowledge regarding clinical research compliance. Her specific research compliance experience includes: implementing process improvements, building/re-designing Clinical Trials Offices, leading government inspections & responses, auditing, monitoring, implementing compliance programs and improving the research billing revenue cycle – from coverage analysis & budgets, authorizations, charge/claims review to denials & appeals management.

Wendy obtained a Bachelor of Science in Nursing from Nicholls State University and a Master of Science in Nursing in Clinical Research Management from Duke University. She also completed a Health Care Corporate Compliance - Post Graduate Certificate Program at George Washington University in Washington, DC and holds several health care related certifications. Wendy has lectured locally, nationally and internationally on various topics related to clinical research, health care auditing and health care compliance.

Statistics of The "Great Resignation"

- The "Great Resignation" lasted more than a year as the number of "Quits" by workers has topped **4 million per month** from November 2021 - December 2022 (ESR Article March 2023)
- The 'Great Resignation' is now the 'Great Regret': **80% of job hoppers wish they hadn't quit their old roles**, with Gen Z the most regretful (Fortune Article February 2023)
- While the majority of employers say they're open to rehiring job-hoppers, some are more hesitant, questioning the loyalty of **boomerang employees** (CNBC Article February 2023)

Question for the Audience

How many employers in the room have rehired or are open to the idea of **rehiring employees who quit** during the period of the Great Resignation?

The Critical Impact of Research Staff Turnover
&
How to Mitigate Potential Compliance Issues

Audience Poll:
What was your staffing turnover rate in the last year?

A. < 10 %
B. 10 – 20 %
C. 21 – 40%
D. 41 – 50%
E. > 50%
F. I have no idea!

What are the top reasons staff are leaving?

A. Money
B. Growth / career advancement
C. Hybrid / work from home opportunity
D. Other

Reasons staff leave

- Money
- Growth / career advancement
- Need more of a challenge
- Burnout
- Work-Life Balance
- Work Environment
- Hybrid
- Structure / Feedback / Value
- Poor Management
- Relocation

Staff Turnover Impact

- Relationships
  - Subjects
    - Trust & recruitment/retention implications
    - Negative experience
  - Sites, Sponsors & CROs
    - Re-work with sites; Study timeline implications
    - Creates additional stress for sites and Sponsors/CROs
    - More…..

Staff Turnover Impact

- Quality & Compliance

  - Compliance error risk, e.g.:

    - Lack of documented informed consent

    - Enrolling ineligible subjects

    - Required reporting failures

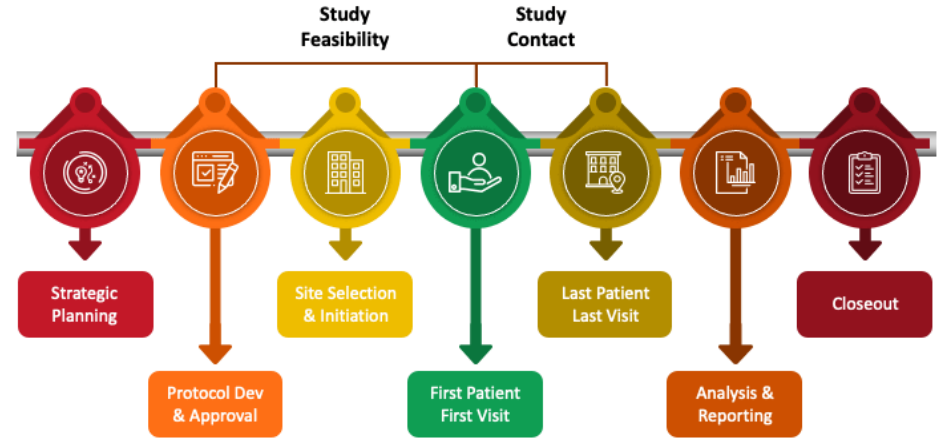 - Lower data quality / integrity

Staff Turnover Impact

- Site Performance

  - Study Timeline lengthening

  - Enrollment goals unmet

CLINICAL TRIAL TIMELINE
Clinical Trial Timeline Schematic

Study Feasibility

Study Contact

Strategic Planning

Protocol Dev & Approval

Site Selection & Initiation

First Patient First Visit

Last Patient Last Visit

Analysis & Reporting

Closeout

Staff Turnover Impact

- Costs
  - Direct Costs
    - New staff hiring, training & onboarding processes
    - Exiting staff = decreased enrollment / revenue
  - Overhead
    - Turnover management
    - Increased operational costs
    - Inflation

How to Mitigate Potential Compliance Issues

Be prepared for staff turnover

- Redundancies
- Formal staff transition plans
- Sub-Investigators
- Study back-up plans
- Study transfer process
- Documented staff roles and responsibilities
- Staff Meetings / Huddles / Check-Ins
- Policies & procedures / tools
- Ongoing QC checks

Does your organization conduct exit interviews?

A. YES
B. NO
C. I DON'T KNOW!

Strategies to Attract, Retain, and Motivate Research Staff
to
Build a Successful Research Program and Lessons Learned

How Are Research Programs Attracting Staff:

- Incentives for Experienced Research Staff:
  - Bonuses: Sign-on/Referral/Quarterly/Annual
  - Tuition Reimbursement
  - Team Culture: Team Bonding Activities & Events
  - Bi-yearly or Quarterly Performance Reviews
  - Upward Mobility/Professional Development Training Programs
    - Career Ladders
  - Cross Training Programs for Different Departments
  - Refresher Training
  - Certification Sponsorship
  - Opportunity for remote/hybrid

How Are Research Programs Attracting Staff Continued:

Restocking the Pond

- "Be creative at sourcing employees from non-site sources. Over the past few years, several Research Organizations have successfully piloted accepting academic degrees in research management, internships, related experience in other disciplines (e.g., project management in non-life science areas), data analytics/management, and other experience as sufficient for entry-level duties." (SCRS Open Letter).
- "Sites are reporting fewer vacant positions, but turnover will persist, and training the newly hired, less experienced research personnel will remain critical." (WCG 2023 Trends & Insights)

How Are Research Programs Attracting Staff Continued:

- ## Where are the Talent?
    - CR Fastrack Programs
    - Health/Science Recent Graduates
    - Talent from Different Therapeutic Areas
    - Research Talent from CRO/Sponsors
    - Non-Research Clinical Staff

Staff Retention and Motivation Topics & Techniques

- Staffing

  - Appropriate staffing levels and staffing mix

- Staff Development

  - Career laddering / Cross training

  - Create staff diversification opportunities, e.g., special projects/programs, training programs
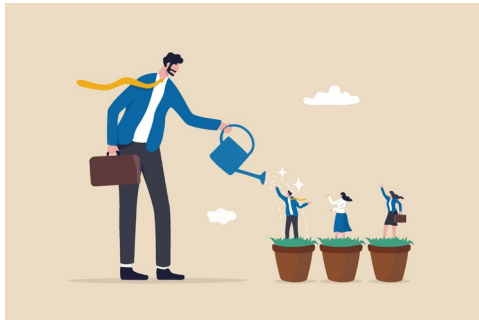
- Operations

  - Change management

  - Portfolio mix monitoring

  - Technology

Staff Retention and Motivation Topics & Techniques

- Metrics
  - Develop / monitor staffing turnover metrics
    - Goal: < 10 -15%
  - Calculate turnover costs
  - Identify and address flight risks – scores, analytics, e.g. Major life changes, feels stuck in job, negative attitude, job hopper, lack of engagement
  - Conduct employee engagement surveys
  - Track results

Challenges, Opportunities, and Successes when
Onboarding New Staff
and
Managing Remote Workers

Does your organization have a formal onboarding program?

A. YES
B. NO
C. NO IDEA

Onboarding:
Challenges, Opportunities & Successes

Challenges:

- No standard onboarding plan
- Funding for training
- Staff shortage
- Misleading job descriptions
- Pre-Boarding
- Neglecting feedback
- Goals & expectations
- Giving too much information too quickly
- Cultural and generational differences

Opportunities & Successes

- The First Day
- Prepare workspace
- Employee Handbook
- Onboarding Policy & Procedure
- Onboarding Plan
  - General – *all Research staff*
  - Role specific
- Assigned mentor / point person
  - Internally
  - Externally
  - Hybrid
- Training Plan - *all and per role*
  - In Person
  - Self-review
  - Quality
- Practice / Implementation / Sign-off
- Refresher training
- Training Resource Library
- Regular check-Ins

Onboarding Plan

NAME:	Instructions			
Job Title:				
Badge #/Employee#:				
Start date:	Some of the tasks in this column can be designated	Remove or update items in BLUE, as applicable		
Direct Report NAME:	Insert Actual Name/Title for each line item		Person who completes the task	
Task	Assigned To Name/Job Title	Date Completed	Initials	Comments / Additional Instructions / Notes

Pre-Start | General - ALL STAFF | NEW | Research Nurse | Study Coordinator | Research Assistant | Regulatory Coordinator | Contract Analyst | **Finance Analyst**

Onboarding Plan

- ● Pre-Start Items
  - ○ HR; Security; Badge; Computer set-up etc.

- ● General - ALL STAFF
  - ○ Set up employee folder in central drive; Tour facilities; Visit with representative in applicable departments/research roles; Review time off; Meetings set-up; Access to applicable research systems etc.

- ● NEW
  - ○ Template

- ● Role Specific
  - ○ Process/ procedures specific to role; study assignments; role assignments; back-up

Does your organization have remote staff?

A. YES
B. NO
C. NO IDEA

What are the top challenges of managing remote staff?

A. Technology Issues
B. Communication Issues
C. Managing Expectations
D. Other

Managing Remote Workers:
Challenges, Opportunities & Successes

Challenges:

- Lack of face-to-face supervision

- Video fatigue

- Lack of information access

- Communication breakdowns

- Interpersonal challenges

- Social isolation

- Home distractions

Opportunities & Successes:
- Establish periodic check-ins
- Provide tools & various communication options; over communicate
- Establish rules of engagement / expectations
    - Establish ASAP
    - Set availability / hours; productivity standards
    - Monitor communication among staff
- Provide social interaction opportunities
- Offer support

32

Managing Remote Workers:
Tips & Best Practices

- Educate leaders/managers/supervisor on managing a remote workforce
- Understand common work from home challenges:
  - Lack of face-to-face interaction, video fatigue, communication breakdowns, distractions
- Set clear remote work productivity standards
- Identify and provide the right tools
- Implement specific days, times and methods for team interaction
- Follow up with remote employees regularly
- Create tip sheet with remote employees' best practices / suggestions
- Communicate! Communicate! Communicate!

Insperity, Managing remote employees: 8 tips and best practices, Cavanaugh- Schroder

Summary

Summary

OPERATIONS:

- Be Pro-Active!!
  - FOCUS ON RETENTION
  - INVEST IN YOUR EMPLOYEES
- Have Onboarding Plans in place
- Staffing contingencies / over staff / back-up
- Transition ready
- Account for turnover
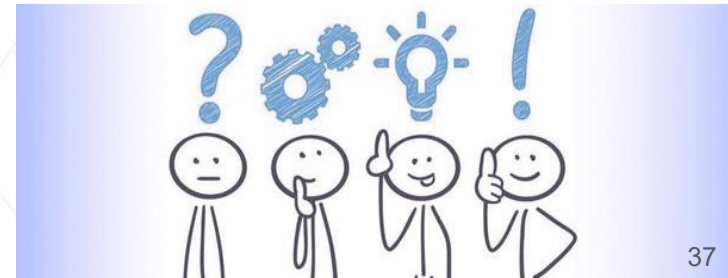- Effectively manage remote employees
- Re-stock the pond

35

Summary

COMPLIANCE:
- Ask the questions and determine:
  - Redundancies
  - Sub-Investigators listed on studies
  - Formal staff transition plans
  - Study transfer processes
  - Documented roles and responsibilities
  - Policies & Procedures / tools
  - Quality Control / Quality Assurance

References

Slide 7
- ESR Article - https://www.esrcheck.com/2023/03/09/great-resignation-slowing-as-under-4-million-workers-quit-in-january-2023/#:~:text=The%20%E2%80%9CGreat%20Resignation%E2%80%9D%20where%20record,by%20the%20U.S.%20Bureau%20of
- Fortune Article - https://fortune.com/2023/02/09/great-resignation-now-great-regret-gen-z-wish-they-had-not-quit-old-job/
- CNBC Article - https://www.cnbc.com/2023/02/02/80percent-of-workers-who-quit-in-great-resignation-regret-it-new-survey.html

Slide 20
- https://myscrs.org/workforce-challenges-letter/
- https://www.wcgclinical.com/clinical-research-trends-insights-for-2023/

Slide 33
- https://www.insperity.com/blog/managing-remote-employees/