Today's outline

- My timeline

- Infrastructure & building trust to support clinical research

- Changing the research culture

- Barriers to recruitment & retention

- PI engagement

- AMC socio-technical ecosystem

- What's at stake if we don't do something?

- Hiring – good humans and talent

Duke Clinical Research
Circa 2000-2012

Fulfilling this Role

- Not reasonable for most staff
- Work a lot for a career ladder that was unclear
  - Highly involved in my oncology RD professional group
  - Cross-collaborative team was supportive
  - If I walked away, the house of cards was going down
- It was tough to build the team out under one PI
  - Funding pressures
  - No clear path for staff to grow

2007

DIY Research

Wendy Demark-Wahnefried, PhD

Contracts
Funding
Project Management
Data security
Data management
Staffing
Grant writing
IRB
Information Technology
Publishing
Compliance
Students
Federal Regulations
Billing

Duke had data problems, staffing issues, fragmented infrastructure – I had a team dedicated to investigator-initiated research in SON

- CTSA formed collaborative partnership with School of Nursing's Research Management Team (RMT)

- School of Medicine explored adoption of the RMT model to address this need

Snyder DC et al. Research Management Team (RMT): A Model for Research Support Services at Duke University. Clin Trans Sci 2012;5(6):464-469

April 2012

REINVENTING research support...Duke Office of Clinical Research (DOCR)

- Ease the navigation challenges through:

  - Investigator support

  - Study team training and development

  - Process improvement

"One stop shop"

Snyder DC, Brouwer R, Ennis CL, Spangler LL, Ainsworth TL, Budinger S, Mullen C, Hawley J, Uhlenbrauck G, Stacy M. Retooling institutional support infrastructure for clinical research. Contemp Clin Trials. 2016 May;48:139-45

Duke Clinical Research *2023*

Vice Dean for Clinical Research

- Duke Office of Clinical Research
  - DEPRU
  - Duke Research@Pickett
- Regulatory Affairs & Quality
- OneDukeBio
  - ODIN

Susanna Naggie, MD
Vice Dean, Clinical Research
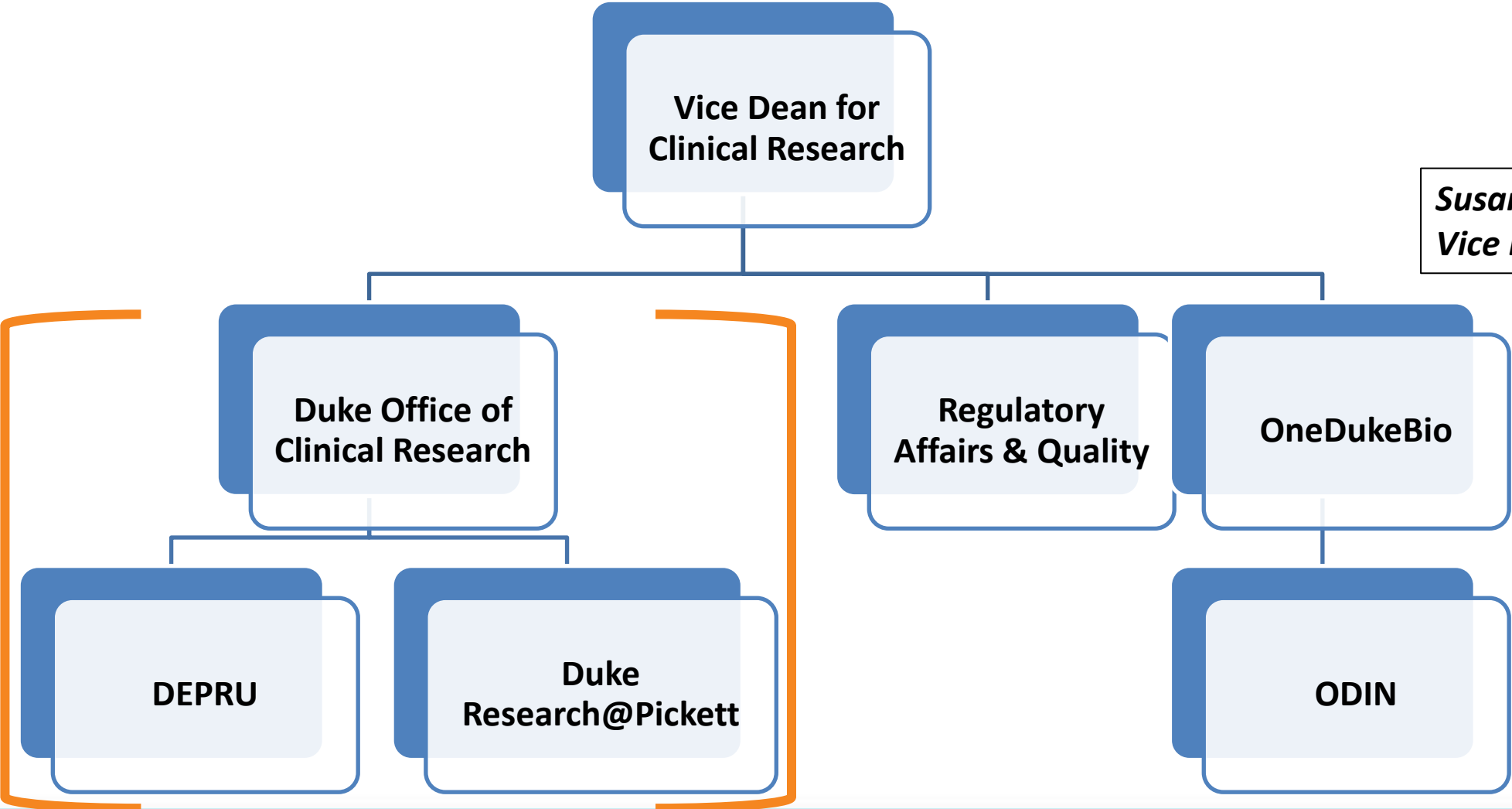
Duke Clinical Research Units (CRU)

Why do we do what we do?

Photo: Duke University Photography
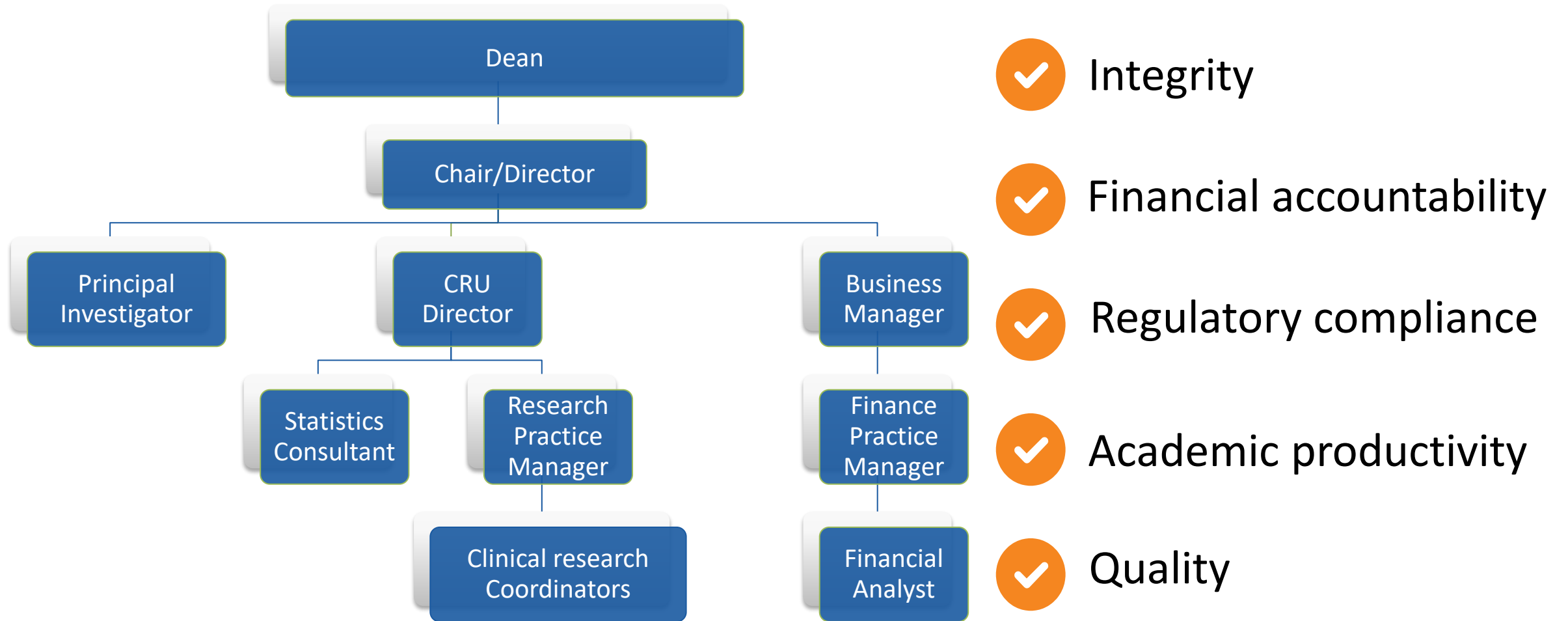
For AMCs, research is a collaboration not a service.

Changing the Research Culture

- Put customer service FIRST

- Inspire staff as a community

- Build partnerships based in trust

- **Required an overhaul of our research jobs**

- **Established career ladders**

- **Need for targeted training and professional development**

Across the US - for every experienced CRC seeking work, there are 7 jobs posted.
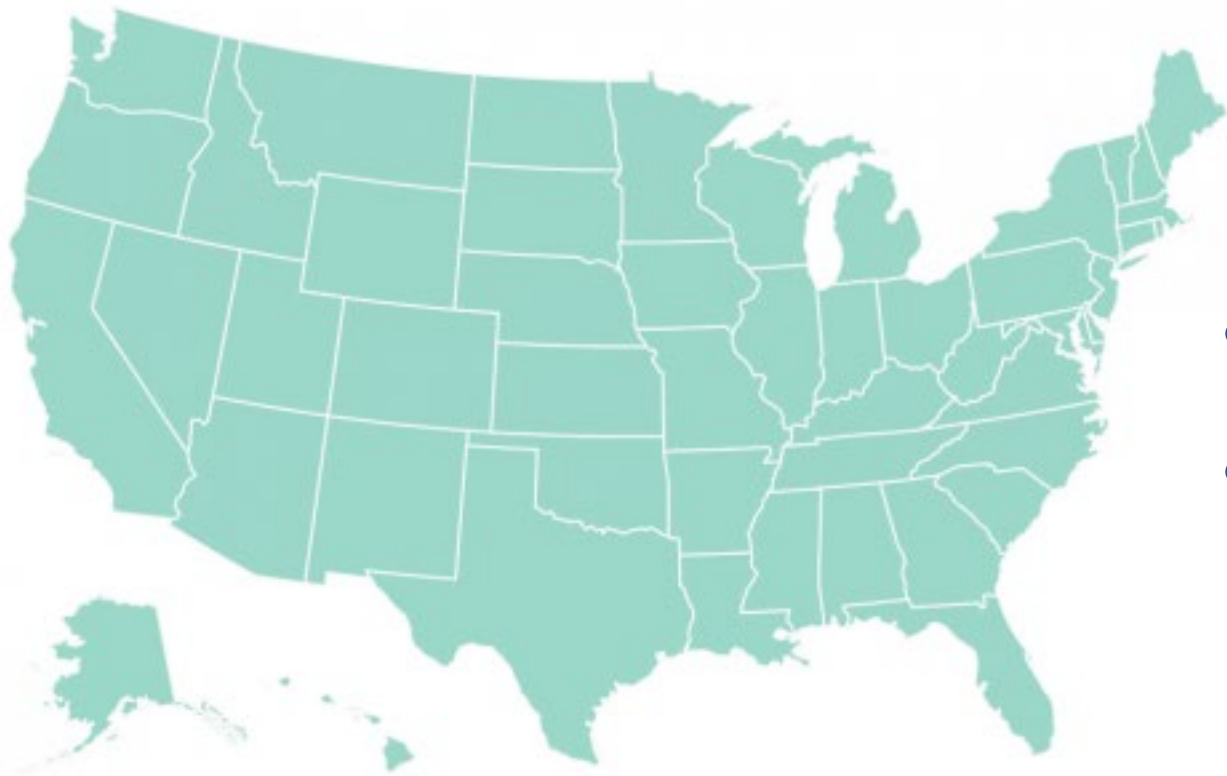
- CRNs - 1:10
- Regulatory affairs - 1:35

https://myscrs.org/resources/sites-now/exploring-the-current-clinical-workforce/

Barriers to successful recruitment and retention of a highly trained and diverse CRP workforce

- Human Resource (HR) department gaps
- Lack of resources
- Lack of institutional support
- Poor Principal Investigator engagement
- Training and professional development gaps
- Outreach to potential new applicants, need for a diverse workforce
- COVID-19 pandemic

Fig. 1. Key barriers.

Knapke, J., Snyder, D., Carter, K., Fitz-Gerald, M., Fritter, J., Kolb, H., . . . Jones, C. (2022). *Issues for recruitment and retention of clinical research professionals at academic medical centers: Part 1 – collaborative conversations Un-Meeting findings. Journal of Clinical and Translational Science, 6(1), E80.*

PI engagement – what are the issues?

- No time to manage staff
- May not understand CRP job titles, duties, or the need for a career ladder - "cogs in the wheel"
- May need training on creating an inclusive environment that **values** CRPs as members of the research team
- High quality staff can positively impact regulatory compliance, data quality, and publication quality
- Inconsistency in the promotion of CRPs, moving staff between tracks based on "cost"

Establish Institutional Training
- Foundational
- Role-based
- Continuing Ed.
Conducting Needs Assessments
Evaluation: Performance Metrics

How to require training?
Identifying CRPs
Centralized vs Departmental

CRP Community of Practice
- Role identify
- Need for learning
- Training accessibility
Protected time
Organizational Support
CRP Worthiness for Training
CRP as Members of CTR Teams
Desire to Grow CRP Brain Trust
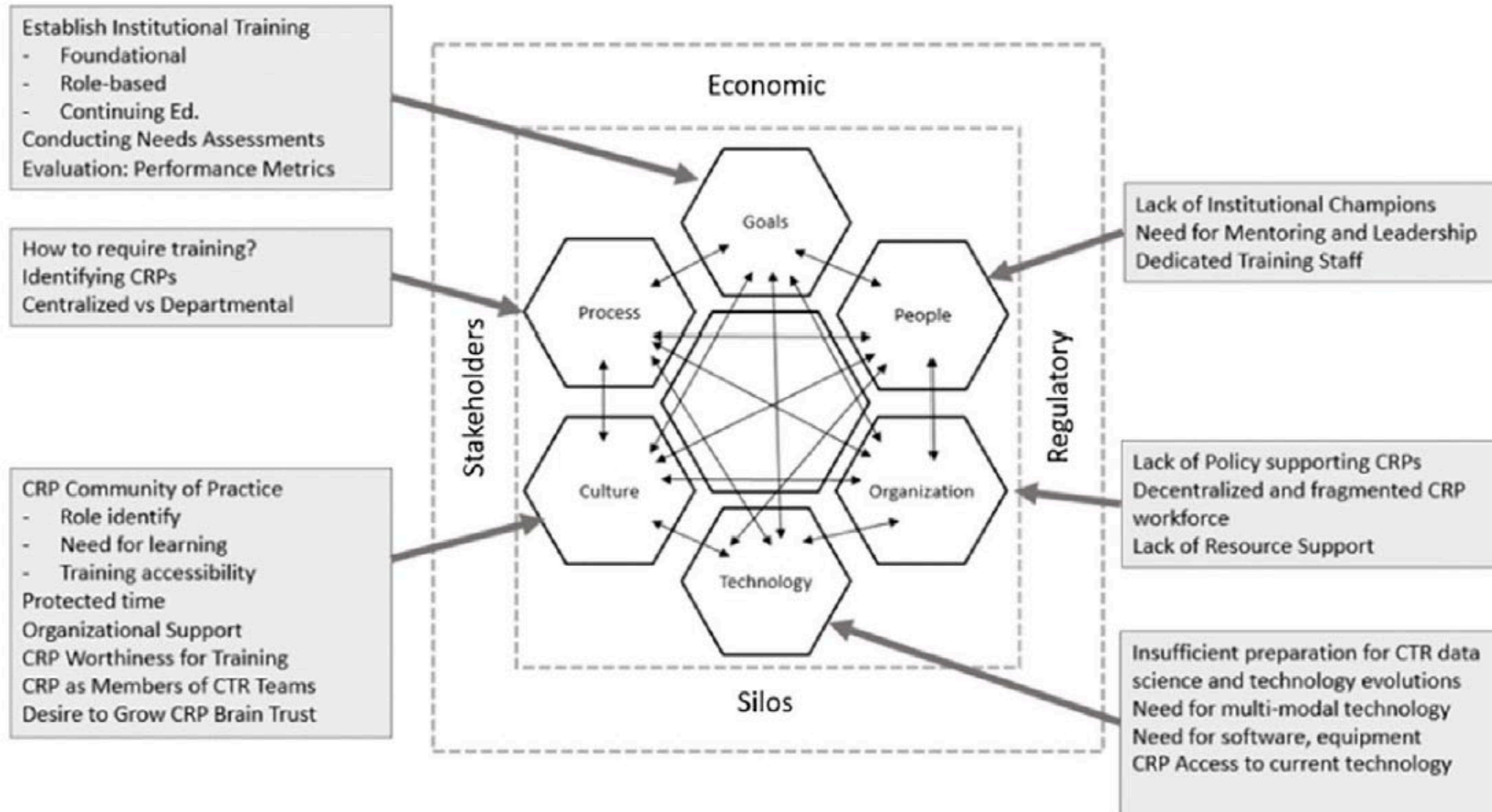
Lack of Institutional Champions
Need for Mentoring and Leadership
Dedicated Training Staff

Lack of Policy supporting CRPs
Decentralized and fragmented CRP
workforce
Lack of Resource Support

Insufficient preparation for CTR data
science and technology evolutions
Need for multi-modal technology
Need for software, equipment
CRP Access to current technology

Economic

Stakeholders

Regulatory

Silos

Goals

Process

People

Culture

Organization

Technology

Fig. 3. Addressing clinical research professional (CRP) training and role development needs in the academic medical center socio-technical ecosystem.

Knapke, J., Jenkerson, M., Tsao, P., Freel, S., Fritter, J., Helm, S., . . . Jones, C. (2022). Academic medical center clinical research professional workforce: Part 2 – Issues in staff onboarding and professional development. Journal of Clinical and Translational Science, 6(1), E81.

HOW?

As an AMC, how do you hire, train, onboard if you don't know who the clinical research professionals are?

Creating a Professional Identity

2014

Joint Task Force for Clinical Trial Competency publishes competency framework with 8 domains. Duke adapts to 12 competency-based job classifications for clinical research professionals.

2016

Clinical Research Professionals Working Group (CRPWG) maps Duke CRPs into job classifications, professional network (RPN) is established, Title Picker Launched.

2018

CRPWG launches advancement pathway. WE-R is established as a program to maintain CR professional development initiatives.

2019

WE-R begins systematically aligning training with competencies and identifying training gaps.

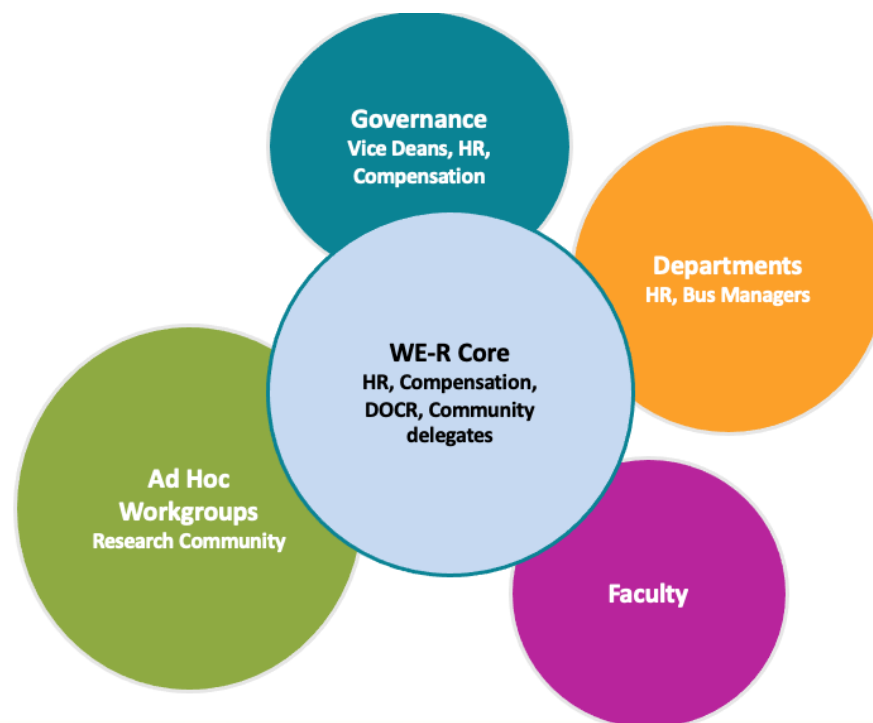**2021**

WE-R launches comprehensive onboarding plans.

2022

WE-R launches new hire co-horts.

2014 – Taking Hold – A Path Forward

JTF Framework

FIGURE 1. Competency Domains for the Clinical Research Professional

1. SCIENTIFIC CONCEPTS AND RESEARCH DESIGN — Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials
2. ETHICAL AND PARTICIPANT SAFETY CONSIDERATIONS — Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial
3. MEDICINES DEVELOPMENT AND REGULATION — Encompasses knowledge of how drugs, devices, and biologicals are developed and regulated
4. CLINICAL TRIALS OPERATIONS (GCPs) — Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, postmarket surveillance, and pharmacovigilance), and handling of investigational product
5. STUDY AND SITE MANAGEMENT — Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs)
6. DATA MANAGEMENT AND INFORMATICS — Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database
7. LEADERSHIP AND PROFESSIONALISM — Encompasses the principles and practice of leadership and professionalism in clinical research
8. COMMUNICATION AND TEAMWORK — Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial
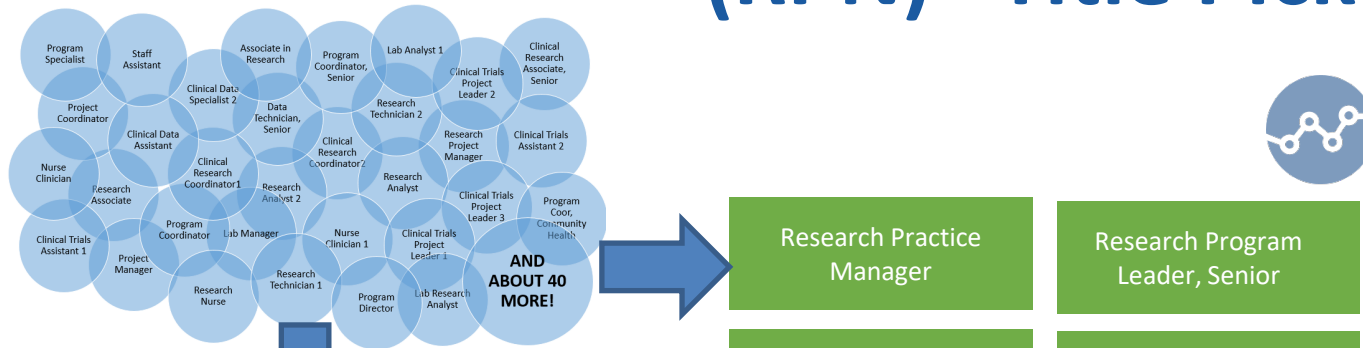
Sonstein S, Seltzer J, Li R, et al. Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. Clin Res. 2014;28(3):17–23.

Leadership Buy-In

Governance — Vice Deans, HR, Compensation

Departments — HR, Bus Managers

WE-R Core — HR, Compensation, DOCR, Community delegates

Ad Hoc Workgroups — Research Community

Faculty

Two Years of Groundwork

Duke-ifying Competencies

- Research Operations
- Safety & Ethics
- Data
- Scientific Concepts
- Site & Study Management
- Leadership & Professionalism

Safety & Ethics

- + Adverse Events
- + Consent Procedures
- + Development of the Informed Consent Documentation and Plan
- + Navigating the Ethics Review Process (IRB)
- + Sponsor/Regulatory Reporting

What did we aim to do?

- Updating job descriptions so they more accurately reflect responsibilities
- Identifying competencies and performance criteria within the classifications
- Defining career ladder and career progression
- Ensuring staff members performing clinical research functions are appropriately classified
- Mapping currently held positions into reworked job classifications
- Incorporating job classifications across Schools of Medicine and Nursing for new hires in these roles

2016 Workforce Mapped, Research Professionals Network (RPN) Title Picker Launched

903 Clinical Research Professionals 45% CRCs (Q3FY23)

Research Practice Manager

Research Program Leader, Senior

Assistant Research Practice Manager

Research Program Leader

Regulatory Coordinator, Senior

Clinical Research Nurse Coordinator, Senior

Clinical Research Coordinator, Senior

Regulatory Coordinator

Clinical Research Nurse Coordinator

Clinical Research Coordinator

Clinical Research Specialist, Senior

Clinical Research Specialist

Brouwer RN et al. (2017). Using Competencies to Transform Clinical Research Job Classifications. Journal of Research Administration. Fall 2017; 48(2):11-25.

REDCap **Title Picker**
Research Electronic Data Capture
provides suggested title based on numerical calculations and rules

2,009 submitted since 2016

Denotes tiered position, which requires competency assessment to advance in tiers

2018 Tier Advancement – Focus on Professional Development

FUN	SKI	ADV	EXP
1	2	4	8

REQUIREMENTS BY TIER

T-1 — < 36 points; default for all new hires

T-2 — Achieve 36-83 points

T-3 — Achieve 84+ points; Approval from committee

Portfolio for committee review

Based on level achieved, candidate receives 1, 2, 4, or 8 points for each competency passed

Deeter C, Hannah D, Reyes C, Mack ME, Stroo M, Freel SA, Brouwer RJN, Gaudaur HE, Doughty AL, Snyder DC. Professional Development for Clinical Research Professionals: Implementation of a Competency-Based Assessment Model. Journal of Research Administration. Spring 2020; 51(2). Epub 2020 September
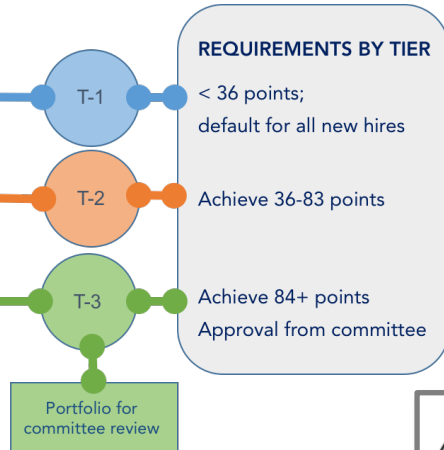
Since 2018, **281** staff have tier advanced

Components:

- Driven by employee
- Build competencies without position change
- Objective measures & proctored testing
- Tier 1 to 2 – **3% raise**
- Tier 2 to 3 – **5% raise**

"I am grateful for your and WE-R's leadership in this program, which supports Duke research professionals like myself and therefore our institution as a whole. I feel it has done a lot to shape our research culture and establish high standards in ethics, professionalism, leadership, compliance, effective and harmonious work, scientific integrity, successful research operations, equity & inclusion, and good clinical practices!"

-Charlotte

2019 Align Training with Competencies

2021 Comprehensive onboarding plans

2022 New hire cohorts

LEARN

BUILD RELATIONSHIPS

1

2

3

4

CRS Express Start Module 1: What is a Clinical Research...

INTRODUCE

RECRUITMENT AND SCREENING

APPLY

62% of new hires volunteer to participate in New Hire cohorts (122 total since Jan 22)

How has WE-R Helped?

- Expand to other areas of clinical research support
  - Clinical Research Data Management (underway) – expected end of calendar year
- Ability to pivot people for immediate research (COVID-19)
  - Floater employee option in DOCR
  - Match project – based on skill inventory from CRPs
  - Dissemination of information and training – easily identified through 12 job classifications
- Employees recognize advancement and growth opportunities
- Budgeted support for WE-R program from CRUs, DOCR, HR & Compensation
- FY22 Market analysis across the WE-R jobs led to 9% adjustment for all CRP positions

How has WE-R Helped?

3-year prior avg 23%

CRU Attrition Rates (Voluntary Terminations)

Attrition Rate / Fiscal Year (FY)

- FY 2018: 15.1%
- FY 2019: 17.0%
- FY 2020: 14.6%
- FY 2021: 19.1%
- FY 2022: 17.9%
- FY 2023**: 10.9%

— All CRUs
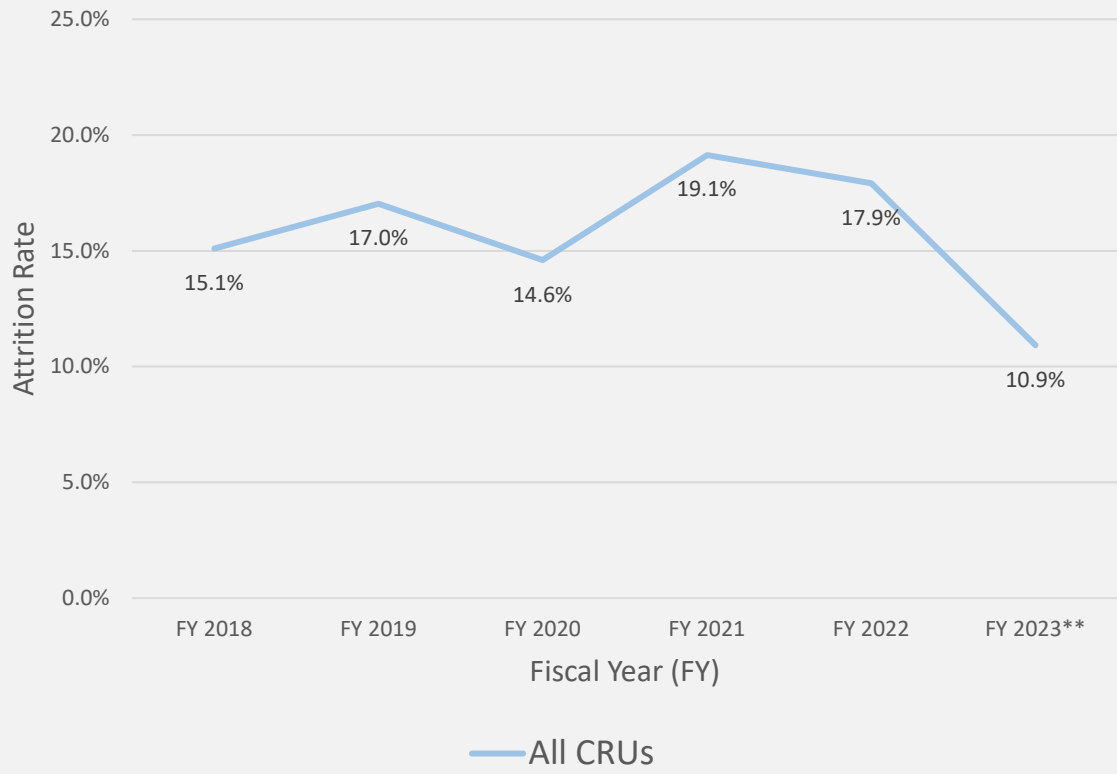
Internal Turbulence Rates (Outgoing Transfers)

Attrition Rate / Fiscal Year (FY)

- FY 2018: 6.2%
- FY 2019: 3.7%
- FY 2020: 4.6%
- FY 2021: 4.8%
- FY 2022: 4.6%
- FY 2023**: 3.9%

— All CRUs
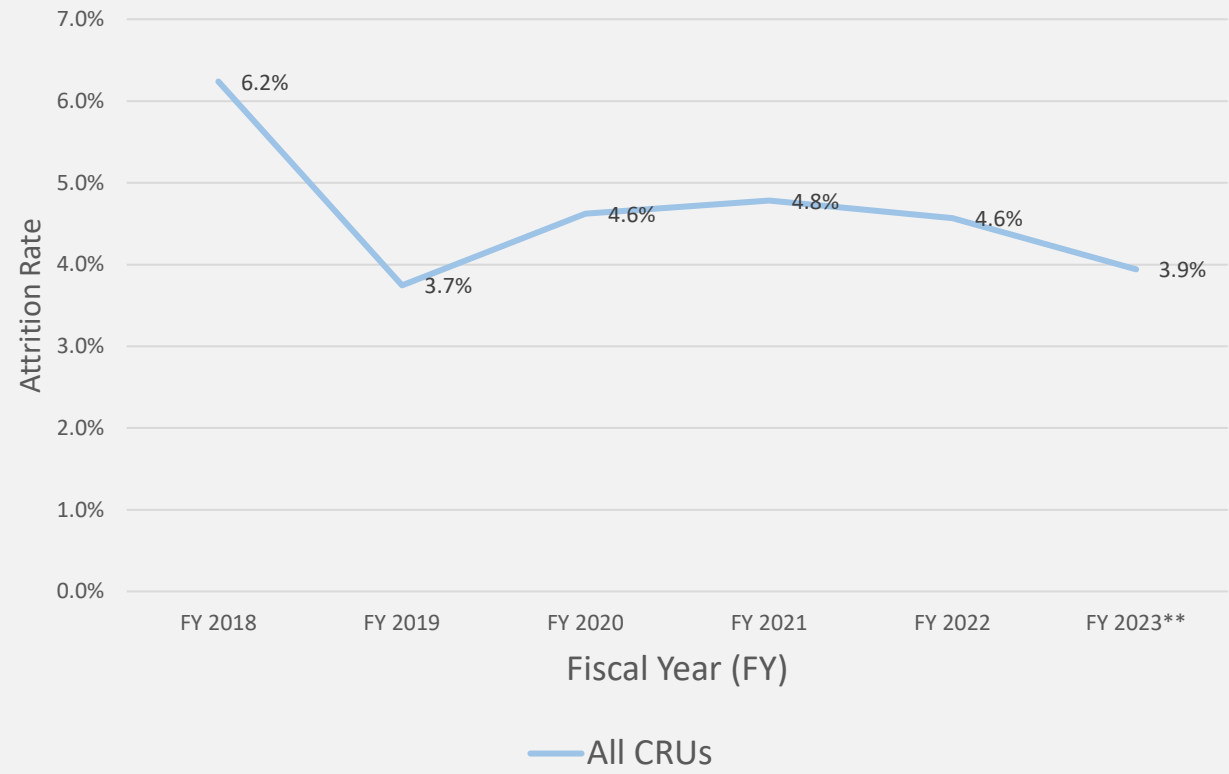
Working with HR

- Make them a partner in the process!
- Bring school and/or enterprise-wide HR in early
  - Allow them to help you frame different functional roles
  - Build leadership support and visibility to the project
- Make room and provide a seat at the table
  - Involve in implementation costing
  - Provide HR data (i.e. Turnover, time to fill, recruitment challenges) to support the cause
- Insight into how to mirror or customize existing processes in other career pathways or clinical ladder processes

What's at stake?

Generating medical evidence – stalls out

SAGE
journals

Perspective

Now is the time to fix the evidence generation system

Robert M Califf iD

Abstract

Despite enormous advances in biomedical science, corresponding improvements in health outcomes lag significantly. This is particularly true in the United States, where life expectancy trails far behind that of other high-income countries. In addition, substantial disparities in life expectancy and other health outcomes exist as a function of race, ethnicity, wealth, education, and geographic location. A major reformation of our national system for generating medical evidence—the clinical research enterprise—

Coming SOON!

Freel, SA, Snyder DC, Bastarache, K, Jones, CT, Marchant, M, Rowley, L, Sonstein, SA, Lipworth, K, Landis , S.
Now is the time to fix the clinical research workforce crisis. *Accepted for publication in Clinical Trials 2023*

A 'Perfect Storm' of Issues

|	
Professional Identity	Lack of a clear professional identity, and lack of recognition as a profession by the US Bureau of Labor & Statistics.
Infrastructure	No standardized pathway into the profession and baseline terminology for clinical research roles, no centrally funded training programs or continuing education, and no mandatory qualifications.
Recognition (VALUED)	'Hidden in plain sight': non-faculty clinical research professionals are generally overlooked as key stakeholders in the clinical research ecosystem.
Remuneration	In contrast with the biotech industry and CROs, pay ceilings at academic medical centers, dictated by static research grants, act as a deterrent to recruiting and retaining staff.
Recruitment	Highly varied hiring requirements and barriers to recruitment, often based on number of years of experience rather than competencies, are further stalling an already strained recruitment process.

The Pressure on the Workforce is Set to Intensify Even Further

Growing number of trials
The number of clinical trials registered worldwide has risen exponentially (from 2,119 in 2000 to 433,207 in 2022) and shows no signs of slowing.[1]
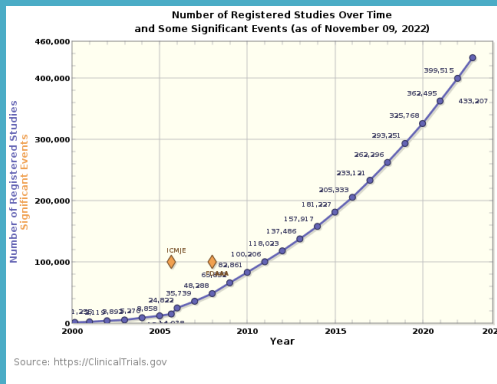
Increasing protocol complexity
A study by the Tufts Center for the Study of Drug Development noted a threefold rise in the number of data points collected in Phase 3 trials over the past decade.

In addition, for all trial phases, an increase in the mean number of protocol deviations and substantial amendments, which are notoriously labor-intensive.[2,3]

Increasingly specialized roles
Surging expectation for trials powered by innovative technology (eg telemedicine, internet-enabled patient wearables) has created new requirements for specialist skills.

In 2022, there was a 28% increase in demand for decentralized clinical trials (DCTs) vs 2021.[4]

In July 2022, close to 30% of all new postings for CR roles didn't fit a traditional job description.[5,6]

1. https://www.clinicaltrials.gov/ct2/resources/trends; 2. https://acrpnet.org/2021/05/05/clinical-trial-complexity-levels-show-unrelenting-increase/; 3. https://www.centerwatch.com/articles/25462-increasing-protocol-complexity-requires-adapting-quality-metrics-tools; 4. https://www.clinicaltrialsarena.com/analysis/2022-forecast-decentralised-trials-to-reach-new-heights-with-28-jump/; 5. https://myscrs.org/resources/sites-now/exploring-the-current-clinical-workforce/; 6. Johnson E. Contemp Clin Trials 2022;120:106878.

Adapted from Clinical Research Workforce Development Global Roundtable, January 12, 2023

Top Priorities

Develop identity and increase awareness of the profession

Support clinical research industry-wide acceptance of entry-level talent

Shift focus from duration of experience to competencies

Create clear pathways for new workforce entrants to gain relevant experience and become aware of truly entry-level jobs

Generate formal communications and public visibility of the workforce crisis

Adapted from Clinical Research Workforce Development Global Roundtable, January 12, 2023

When the CRP decides to leave

What now?

Departures Lead to Hiring Opportunities

- Examine your team's needs
  - What's missing?
  - What has changed?
  - What initiatives are planned?
  - Is it time to backfill? Do you pause? Rework the job?
- Reassess position
  - What do you want this person to do?
  - What strengths or talents are you looking for?
  - What are the team dynamics?

Recruitment & Hiring – What About "Talent" ?

- **Talent definition:** natural aptitude, an inner quality emerges without effort

- **Skill definition:** an acquired ability, learned with effort

- Research suggests genes play a role forming the way individuals respond to stimuli and seek out specific experiences.

- The environment is equally important for talent identification and development. A talent becomes an enduring ability only with effort and practice.

Talent (& Skill) Examples

- Writing
- Researching
- Brainstorming
- Inspiring
- Self-managing
- Networking
- Innovating

- Listening
- Negotiating
- Programming
- Rational thought, emotional intelligence, visual thinking, decision making, and situational intelligence
- Exceptional intuition and skill

Recruitment & Hiring – Talent

- **Be specific about talents and skills you're looking for.**
  – Identify all the skills that will help an employee to shine in a particular role.
  – Distinguish between must-haves and nice-to-haves.
- **Look beyond typical requirements.**
  – Previous work experience and education are not always reliable criteria.
  – Look at <u>hobbies and interests in candidates' resumes</u>.
  – Turn to your network for referrals.
- **Interviews matter.**
  – Prepare, prepare, prepare.
  – Ask all candidates talent- and skill-relevant questions.
- **Identify candidates' mental strengths.**
  – Look for resilience, grit, and positive mindset.
  – Use the <u>STARR model</u> (Situation, Task, Action, Result, and Reflection).
  – Ask behavior focused questions.

Hiring – General Considerations

- **Relevant education and experience**
  - Do you need someone with a background in clinical research, can you teach the skills? Team-oriented? Systems knowledge (OnCore, eReg, REDCap, <fill in your software>?)
- **Strong communication skills**
  - Role requires regular interaction with study research teams and other staff across your AMC (e.g., IRB)
  - Excellent verbal and written communication skills
  - Able to effectively communicate complex information
- **Attention to detail**
  - Documentation, date entry, regulatory, protocols…details matter
- **Adaptability**
  - Hire individuals who are adaptable and open to new ideas and approaches.
  - Consider individuals who have a willingness to learn and grow in their role
- **Ethical conduct**
  - Hire individuals who are trustworthy and have a strong commitment to ethical conduct

Hiring – What else matters? Good Humans

- Our team matters – we do not want to hire people who think they are better than the team. We are better together.

- We believe research changes care – everyone's role in clinical research elevates our ability to conduct trials that change the standard of care.

- Good humans are kind to all people.

Onboarding

- We have a central SOP that we follow for all team members to onboard
- Individual teams have job specific training plans
- Combination of independent learning and 1:1 training side by side with a mentor
- Daily touch points, especially in this virtual world
- Quickly make them feel part of the team
- Give them a soft landing!

Be Engaged - Encourage Development - Prevent Burnout

- Take the lead in change

- Provide opportunities to present internally - start small with team meetings

- Look for innovative improvements that can be shared internally

- Consider submitting abstracts for posters or presentations

- Encourage staff to get involved in external consortiums, peer AMC groups

- Oversee workload – encourage communication

Make Clinical Research More Human – What Matters?

- Establish meaningful connections through the work we do

- Share the same values

- Compensate fairly for work and above-and-beyond efforts

- Assist in building in their skills

- Provide necessary support to flourish without burning out

Takeaways

- Timing of infrastructure & building trust
- Changing the research culture
- Barriers to recruitment & retention of staff
- Consider competency-based jobs with career ladders
- How do you get involved?
- What's at stake if we don't do something?
- Hiring – good humans and talent

Thank you!