MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Joint Task Force for Clinical Trial Competency (JTF)

Biannual Global Meeting

2 June 2025

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Introduction

Barbara Bierer, MD
Faculty Director, MRCT Center
Co-Chair, JTF
Stephen Sonstein, PhD
Co-Chair, JTF

This Meeting

We are recording this meeting for note-taking purposes.

We plan to post slides and an executive summary of the meeting on the JTF website.

We will follow up regarding permission with the presenters.

Disclaimer

The opinions contained herein are those of the presenters and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or any of the institutions or organizations represented today.

The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions, and government entities (see www.MRCTCenter.org) and by grants.

We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center leadership retains responsibility and final control of the content of any products, results, and deliverables.

We have no personal financial conflicts of interest with the content of this presentation

About Us

MRCT Center is an applied policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials around the world.

Global Standards for Clinical Research Professionals

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

The JTF has identified the knowledge and skills required for **safe, ethical, and high-quality clinical research.**

We are committed to providing all members of the research team worldwide with **guidance and tools to ensure necessary competencies**.

www.mrctcenter.org/clinical-trial-competency

The 8 JTF Competency Domains

Scientific Concepts and Research Design

Knowledge of scientific concepts related to the design and analysis of clinical trials

Ethical & Participant Safety Considerations

Care of patients, human participant protections, and safety in the conduct of a clinical trial

Medicines Development and Regulation

Knowledge of how drugs, devices, and biologicals are developed and regulated

Clinical Trial Operations (GCPs)

Study management and GCP compliance; safety management and handling of investigational product

Study and Site Management

Content required at the site level to run a study including site and study operations

Data Management and Informatics

How data are acquired and managed during a clinical trial, including source data, data entry, queries, etc.

Leadership and Professionalism

The principles and practice of leadership and professionalism in clinical research

Communication and Teamwork

All communication within the site and between sites, sponsor, & CRO

Under each domain are specific competency statements

FOR EXAMPLE:

Domain 1: Scientific Concepts and Research Design

Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials

1.1 Apply principles of biomedical science to investigational product discovery and development and health- related behavioral interventions

1.2 Identify scientific questions that are potentially testable clinical research hypotheses

1.3 Identify the elements and explain the principles and processes of designing a clinical study

1.4 Maintain awareness of new technologies, methodologies, and techniques that enhance the conduct, safety, and validity of the clinical study

1.5 Critically analyze clinical study results

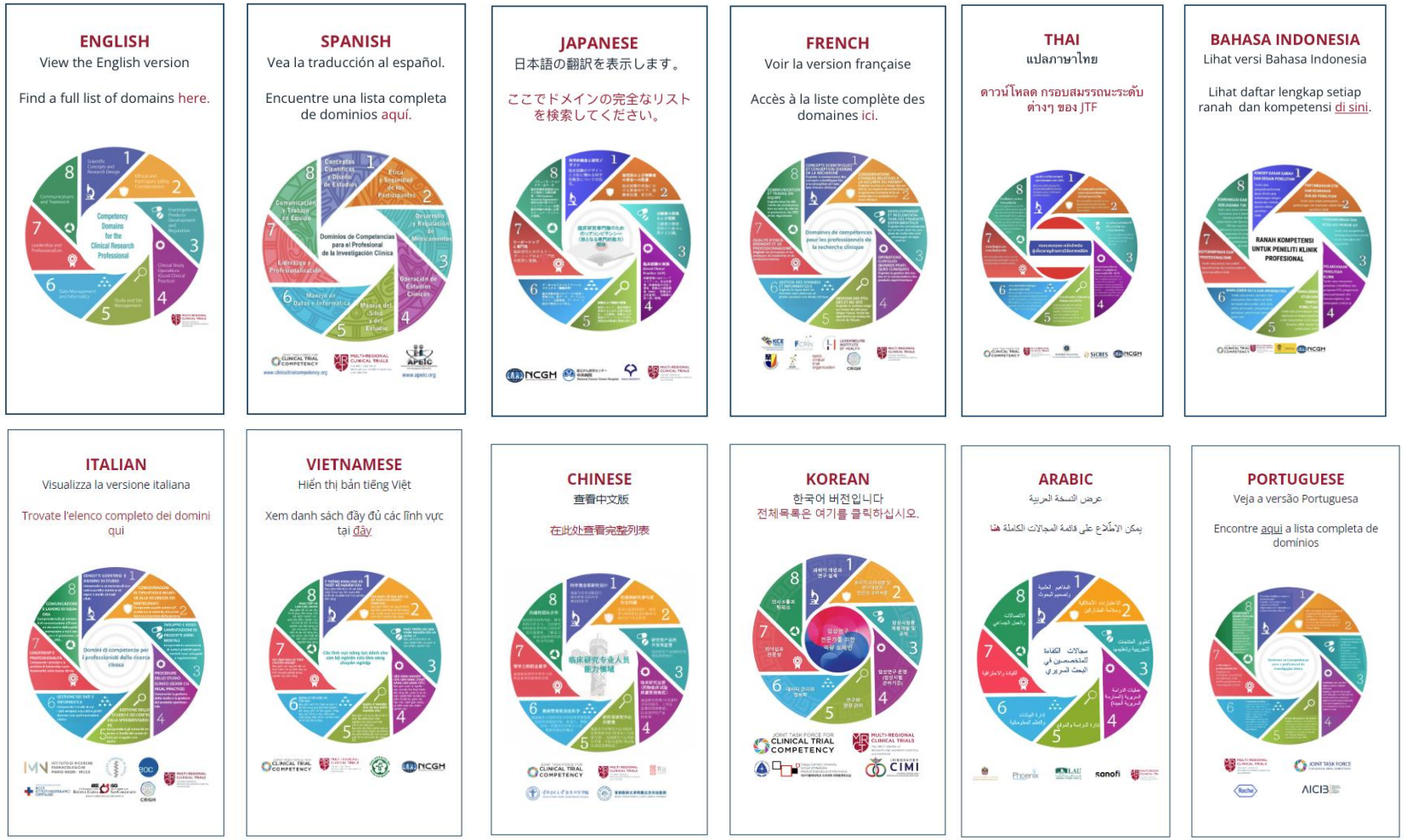
Competencies are reflected at a Basic, Skilled, and Advanced level

1.1 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions

Fundamental Level	Skilled Level	Advanced Level
A1. Recognize the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions	**B1. Apply** scientific principles when implementing a clinical or behavioral study	**C1. Plan** biomedical research according to scientific principles
A2. Explain the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions	**B2. Implement** data collection according to scientific principles and based on protocol design	**C2. Develop** a data management plan according to scientific principles.
Example: When reviewing a clinical research protocol, researcher describes the objective and scientific techniques used to design and implement biomedical research.	**Example:** When given a clinical research protocol, researcher differentiates what principles could affect how the data should be collected and implement best practices accordingly.	**Example:** Given a clinical research protocol and data collected, the researcher evaluates the findings to assess results via a scientific framework.

Translations that are currently available:

- English
- Spanish
- Japanese
- French
- Thai
- Bahasa Indonesia
- Italian
- Vietnamese
- Chinese
- Korean
- Arabic
- Portuguese



https://mrctcenter.org/clinical-trial competency/framework/translations/

How to reference the MRCT Center when using the JTF Framework

Joint Task Force for Clinical Trial Competency (JTF)

Agenda

Time EDT	Topic	Speaker / Facilitator
9:00-9:10	Welcome and Introduction Update from JTF Webinar April 3	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center **Stephen Sonstein, PhD** Co-Chair, JTF Consultant, MRCT Center
9:10-9:35	Integrating JTF Competencies: Curriculum Design and Accreditation	**Kaushal Shah, PhD** Program Director, Clinical Research Management and Regulatory Science Programs Arizona State University
9:35-10:00	Comprehensive leveling of the Clinical Research Professional Career Ladder at Johns Hopkins University	**Anthony (Tony) Keyes, MBA, PMP** Assistant Director of Research Workforce Operations Johns Hopkins Institute for Clinical & Translational Research

Agenda (cont.)

Time EST	Topic	Speaker / Facilitator
10:00-10:25	Data Management Competencies: Results from Delphi	**Meredith Zozus, PhD** Professor, Division Chief, Clinical Research Informatics University of Texas (UT) Health San Antonio, Long School of Medicine, Department of Population Health Sciences
10:25-10:50	JTF-P3 (Patient Partner Project) Update	**Sylvia Baedorf Kassis, MPH** Program Director MRCT Center & **Linda Hunter** National Manager of the Patient and Community Partner Stream, Grant Co-Applicant CANTRAIN
10:50-11:00	Discussion and Wrap-up	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center

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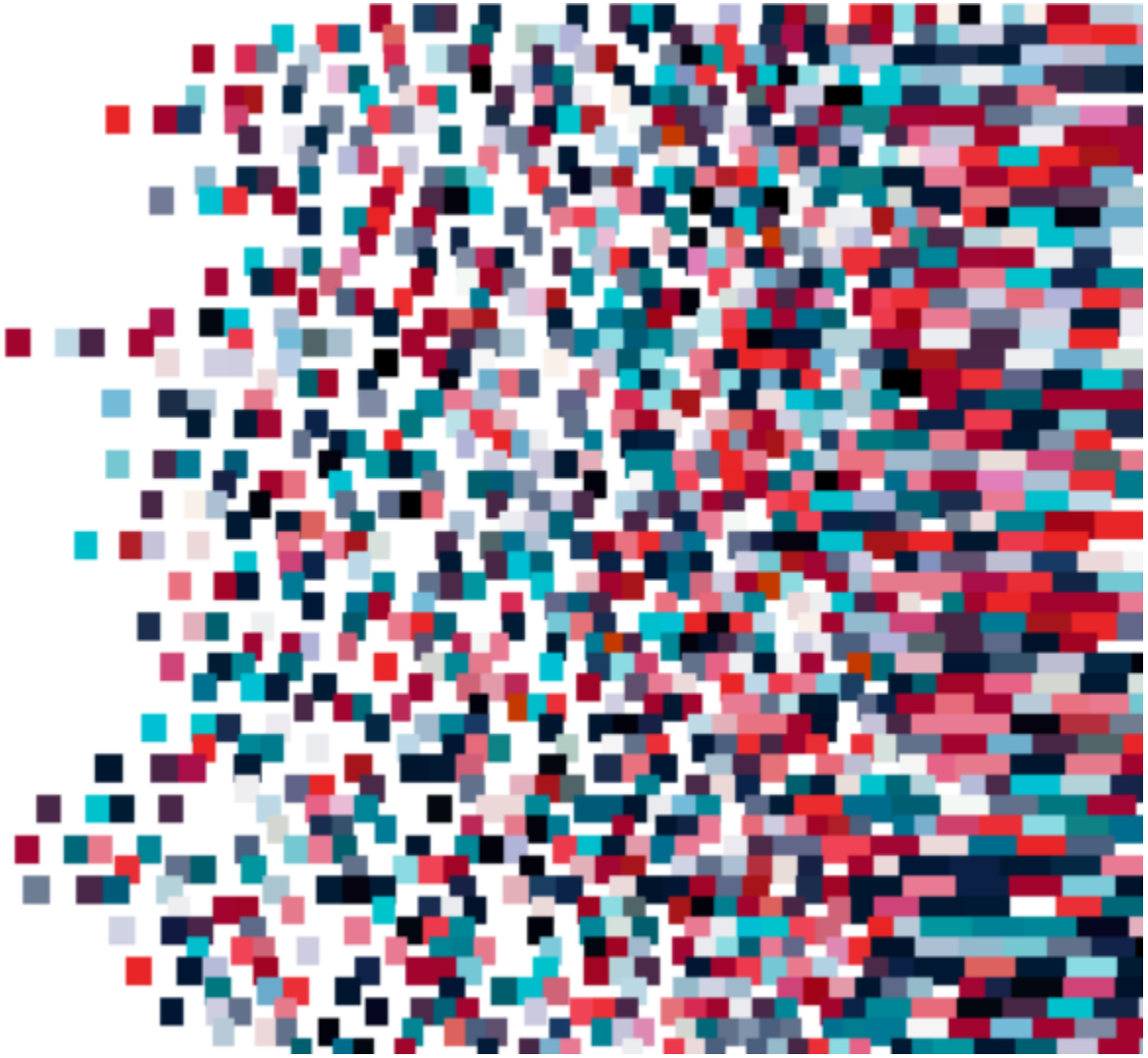
Webinar:

Global Development of a Clinical Research Workforce: Tools and Resources

AVAILABLE ON DEMAND



https://mrctcenter.org/resource/global-development-of-clinical-research-workforce-tools-and-resources/

Next JTF Biannual Global Meeting

10 December 2025, 1:00-3:00 PM EST

Please note different timeframe to allow people from different time zones to participate

Registration will be available later this year

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Integrating JTF Competencies: Curriculum Design and Accreditation

Kaushal Shah, PhD

Program Director, Clinical Research Management and Regulatory Science Programs

Arizona State University

Integrating JTF Competencies

Curriculum design and accreditation

Kaushal Shah

June 2nd 2025

Industry Roles

Worked in pharmaceutical and consulting roles

Product Expertise

Expertise in pharmaceuticals, biologics, and medical devices

Conference Chair

Organizes premier clinical research conference in Phoenix

International Experience

Has worked in various global regulatory environments

ACRP-PHX President

Leads professional organization in Phoenix

AGRE Board Member

Serves on the board of global educators

Program Director

Oversees CRM and Regulatory Science programs at ASU

1st Accredited CRM program

20+ Nationality of our participants

25+ Global faculty members

Masters Programs

- Clinical Research Management
- Regulatory Science
- CRM with Reg Science
- Reg Science with Food Safety

DPP in Regulatory and CRM

Certificate Programs

Why JTF at ASU

1 **Establish Standard**

Align with JTF competencies for professional endorsement.

2 **Clarify Expectations**

Define learning tiers to guide student development.

3 **Support Curriculum Design**

Use JTF framework for outcome-based curriculum.

4 **Improve Readiness**

Train students in JTF domains for workplace impact.

5 **Facilitate Accreditation**

Meet accreditation requirements with JTF benchmarks.

CRM program outcomes

Global Trends Analysis

Understanding historical and ethical frameworks in research

Ethical Conduct

Aligning research ethics with regulations

Risk Assessment

Evaluating risk levels for research and subject safety

Compliance with GCP

Ensuring clinical trials adhere to good clinical practices

Industry Forms and Contracts

Analyzing standard documents in clinical research

Medical Product Development

Understanding processes for commercial distribution

Data Management

Managing and integrating data from diverse trials

Performance Measurement

Assessing work performance and taking corrective actions

Leadership Development

Building leadership capacity in interprofessional teams

Adverse Event Reporting

Identifying and reporting adverse events effectively

Course snapshot

HCR 123

		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
Course Outcome 1	PO1, PO3	Assgn 1			Assgn 4 MT			
Course Outcome 2	PO4, PO6		DB 2		MT	DB 5		

JTF Mapping

	JTF #1	JTF #2	JTF #3	JTF #4	JTF #5	JTF #6	JTF #7	JTF #8
Program Outcome 1		HCR 123 HCR 124			HCR 123	HCR 231		
Program Outcome 2			HCR 231				HCR 124	

JTF and accreditation

Characteristic	Accreditation
Standards Alignment	Direct address of CAAHEP criteria
Documentation	Straightforward compliance documentation
Best Practices	Signals commitment to workforce development
Continuous Improvement	Easier adaptation to future needs

Reflection and Takeaways

The way forward

Engage Stakeholders

Advisory boards and partners

Implement JTF Competencies

Assess, map and improve

Maintain Accreditation

Excel on all standards

Raise the Bar

Commit to excellence

Thank you

kaushal.p.shah@asu.edu

Arizona State University

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Comprehensive Leveling of the Clinical Research Professional Career Ladder at Johns Hopkins University

Anthony (Tony) Keyes, MBA, PMP

Assistant Director of Research Workforce Operations

Johns Hopkins Institute for Clinical & Translational Research

JTF Biannual Global Meeting 2 June 2025

JTF Biannual Global Meeting Panel

Comprehensive Leveling of the Clinical Research Professional Career Ladder at Johns Hopkins University

Anthony Keyes, MBA, PMP
Assistant Director, Clinical Workforce Operations

June 2, 2025

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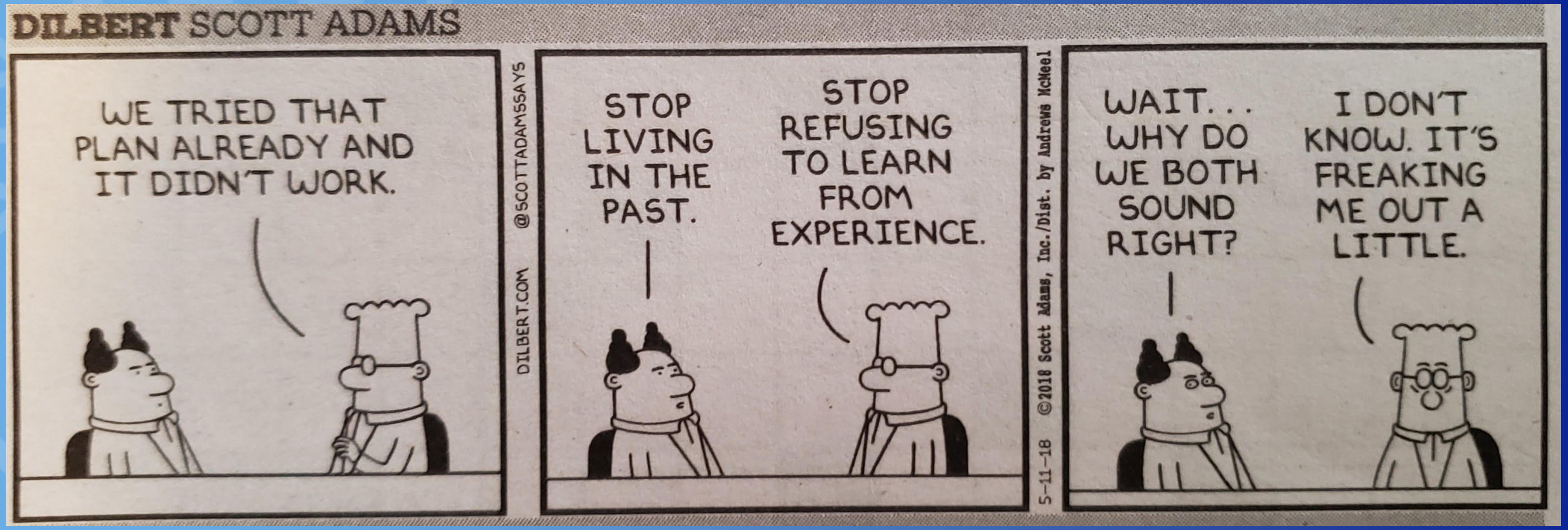
Untenable Situation (2017-2018)

- Decentralized staffing model - hiring/advancement based on finances
- Departmental equity varied greatly
- Declining net compensation
- Misalignment with role titles/actual duties
- Good Coordinators leaving for better opportunity or small pay increases
- No ability to identify targeted audiences

- Various previous attempts to address had failed…


DILBERT SCOTT ADAMS
WE TRIED THAT PLAN ALREADY AND IT DIDN'T WORK.
DILBERT.COM @SCOTTADAMSSAYS
STOP LIVING IN THE PAST.
STOP REFUSING TO LEARN FROM EXPERIENCE.
5-11-18 ©2018 Scott Adams, Inc./Dist. by Andrews McMeel
WAIT... WHY DO WE BOTH SOUND RIGHT?
I DON'T KNOW. IT'S FREAKING ME OUT A LITTLE.

Business Case

- Institutional priorities:
  - —Aligned with the School of Medicine *Strategic Plan*, “people” priority
  - —Hire, retain and advance research staff
  - —Ensure staff had the appropriate title and pay scale
  - —Establish a defined career pathway based on competencies
  - —Reduce Turnover

  - —Project Charter approval (accountable to quarterly Best Practice Committee)

Needs → Project Goals

1. Develop standardized job descriptions across the Research Coordinator Career Ladder (equity)
2. Identify and align job descriptions with competencies
3. Effectively characterize research groups (for targeted communication, trainings, etc.)
4. Perform benchmarking survey for salary adjustment (decrease turnover/makes JHU more competitive)

Team Member(s):

- Bonnie Guralnick; Human Resources, Sr. Compensation Analyst
- Liz Martinez; Sr. Research Nurse, Research Participant Advocate
- Anthony Keyes; Program Manager, Clinical Research Projects
- Stephanie Swords; Program Manager, SCAMP Program

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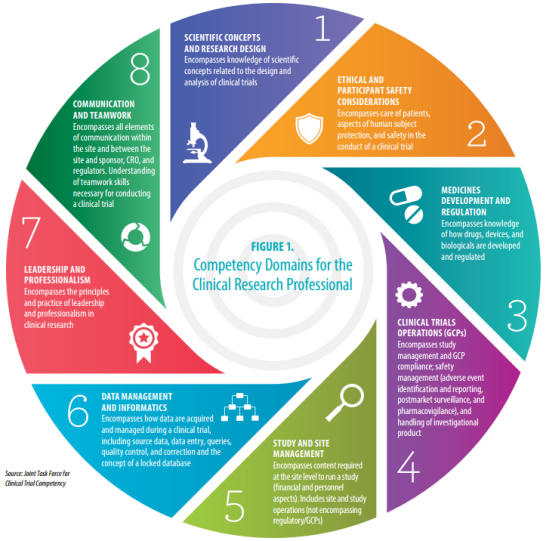
Shoulders of Giants

- Duke (Title Mapping & Title Picker REDCap)
- National Research Coordinator Consortium (NRCC)

Core Competency Framework for the Clinical Research Professional, Version 3.0 FUNDAMENTAL, SKILLED and ADVANCED LEVEL		
A. Fundamental Level	**B. Skilled Level**	**C. Advanced Level**



NRCC is now the Clinical Research Professional Taskforce (CRPT)

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Title Alignment

Tier	C			
Standardized Title	Research Program Coordinator			
add "Clinical"	Clinical Research Program Coordinator			
Potential former titles [number of staff (full-time/part-time)]	Research Program Coordinator	234	34	CD Pay Range
	Research Assistant (focused on data analysis)	77	34	CD Pay Grade
Total number of staff in all former titles	379			
Total number of staff to standardize	111			
Job Family (NEW)	Research - Clinical			
Role	ACRP			
Level	2			
Pay Grade (FY 2018)	CD			
Job FLSA Indicator	Non-Exempt			
Required Education	Batchelor's Degree			
Required Experience	≥2 years experience in clinical research			
Education/Experience Equivalency	≥2 years experience in clinical research AND Certification through SoCRA (CCRP) or ACRP (CCRP, CCRA)			

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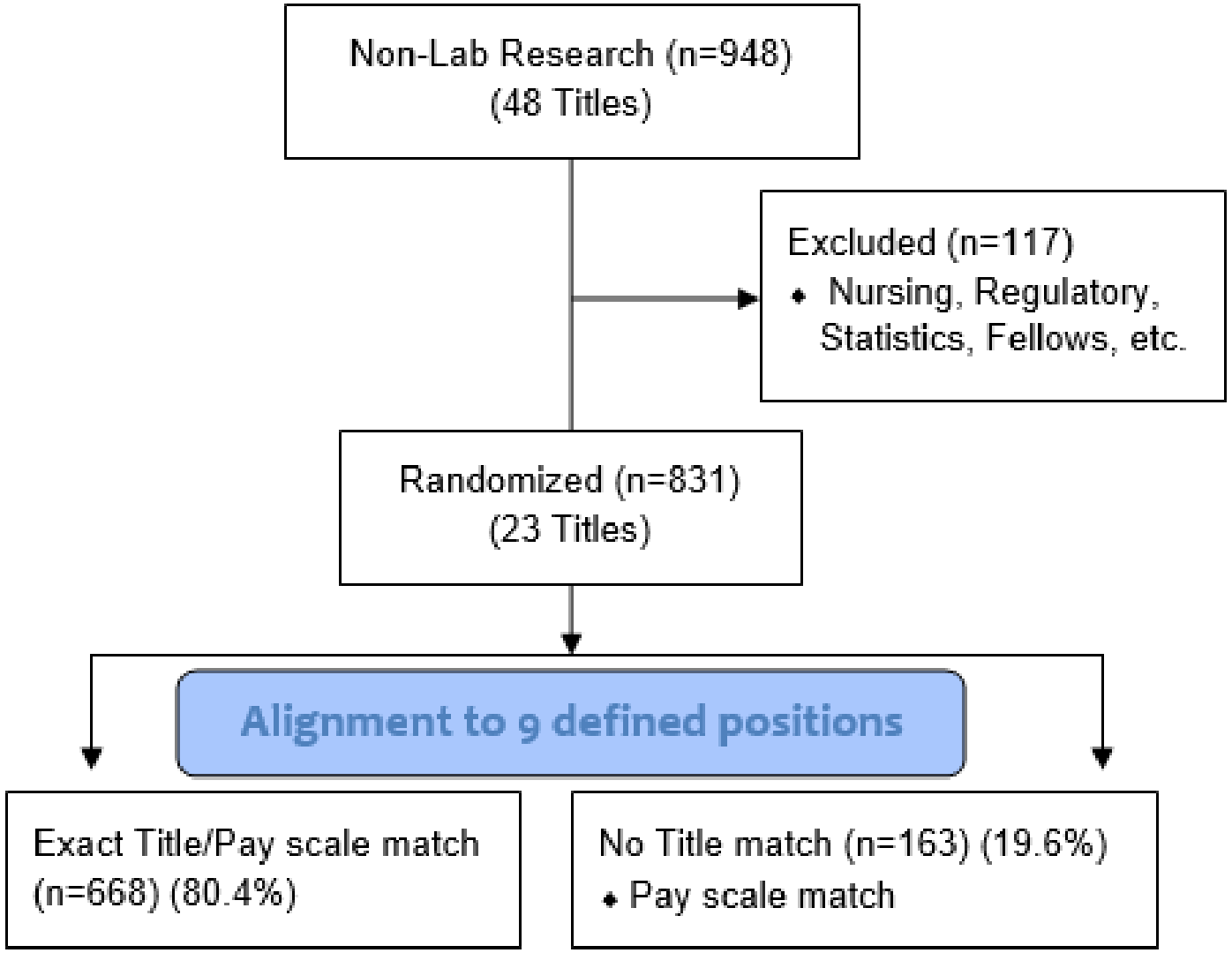
Define our Population



- Worked with HR to obtain a list of the total non-lab, research positions
- Defined 9 positions (new job family?)
- Identified the number of positions that would need to be aligned

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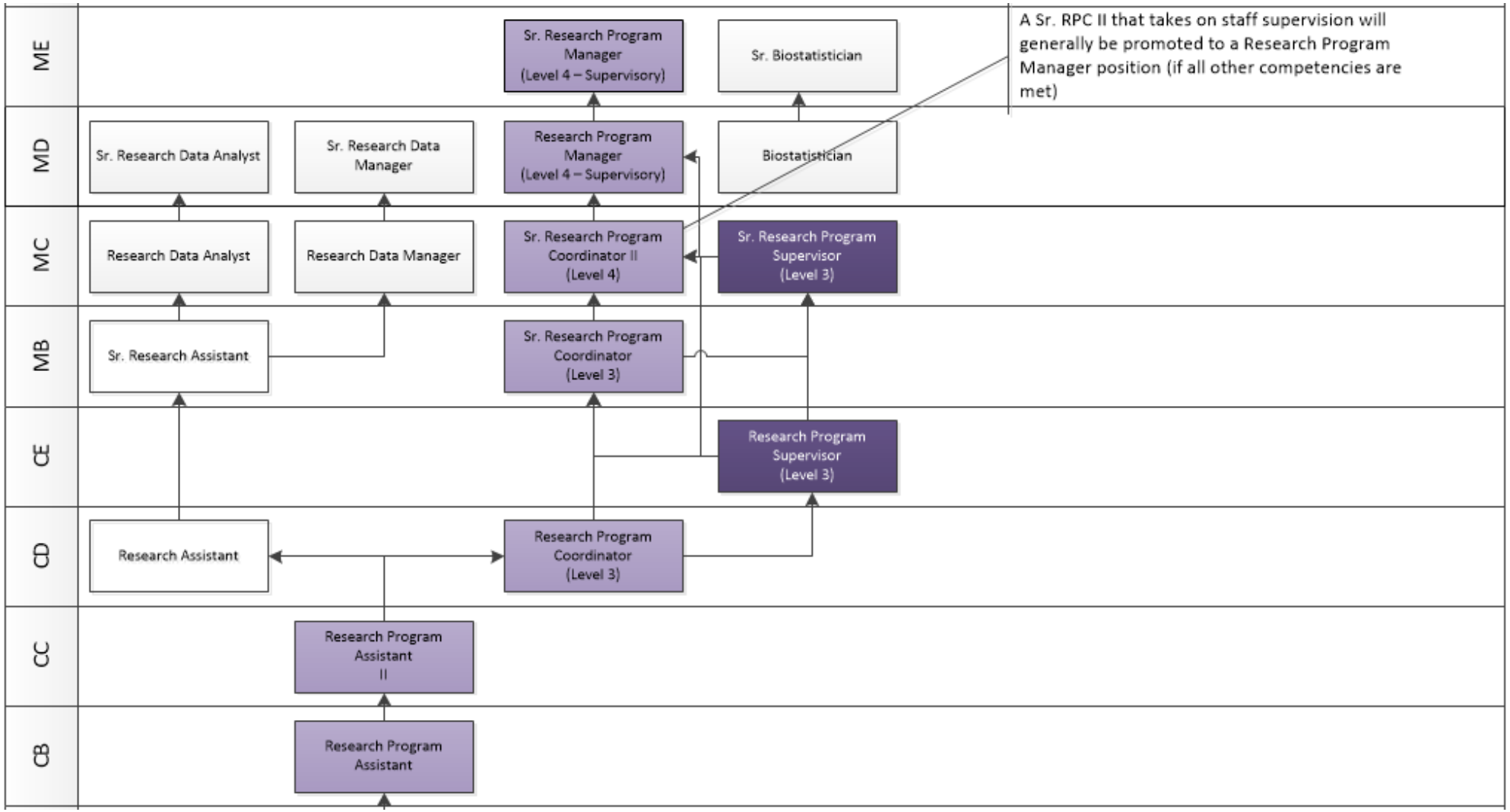
Not just a Ladder, a Network



- Assistant
- Assistant II
- Coordinator
- **Supervisor**
- Sr. Coordinator
- **Sr. Supervisor**
- Sr Coord. II
- Manager
- Sr. Manager

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Competency Alignment Grid

- Existing JHU Duties
- Revised JHU Competencies

-PLUS-

- ACRP (Entry-level, Intermediate, Senior)
- Joint Taskforce V 3.0 (Fundamental, Skilled, Advanced)
- Duke (CRC, Tier 1, 2, 3, Senior)
- Discussions with the Clinical Research Professional Taskforce (CRPT)
- Many conversations with other Academic Medical Centers

Competency Alignment

Domain	Competency	New JHU Competency Chart (2019)	Prior JHU Grid (2011)	ACRP			Joint Task Force V3.0			Duke				
				Entry Level CRC	Intermediate CRC	Senior CRC	A. Fundamental Level	B. Skilled Level	C. Advanced Level	CRC/CRNC or Reg	Tier 1	Tier 2	Tier 3	CRC/CRNC, Sr or Reg.
Scientific Concepts and Research Design	**1.1 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions**	Explain the study background and		Describe the various types of	Explain both basic and more	Guide study team members	A1. Recognize the need to apply scientific principles to	B1. Apply scientific principles when implementing a	C1. Plan biomedical research according to	Demonstrates a basic understan	Scores at least 60% on knowledge	Scores at least 80% on knowledge	Scores at least 90% on knowledge	Provides significant contributi on to
				Explain the study backgrou nd and	Demonstr ate an understan ding of	Demonstr ate the ability to guide	A2. Explain the basic scientific principles that should be	B2. Implement data collection according to scientific	C2. Develop a data management plan according					
				Explain the purpose of an	Demonstr ate the ability to describe	Support study team members								
	1.2 Identify **scientific questions** that are potentially testable clinical research hypotheses	Identify the research hypothesis in a study	Conduct literature searches to provide	Identify and explain the study	Demonstr ate an understan ding of	Analyze protocols to identify study	A1. Articulate the purpose of the study	B1. Identify the research hypothesis in a study protocol	C1. Develop protocol or source document	Conducts literature searches and	Identifies search terms, knows	Narrows searches to those articles	Identifies and articulates overall	
							A2. Describe the importance of the study	B2. Identify endpoints (primary and	C2. Align parameters for collecting data					

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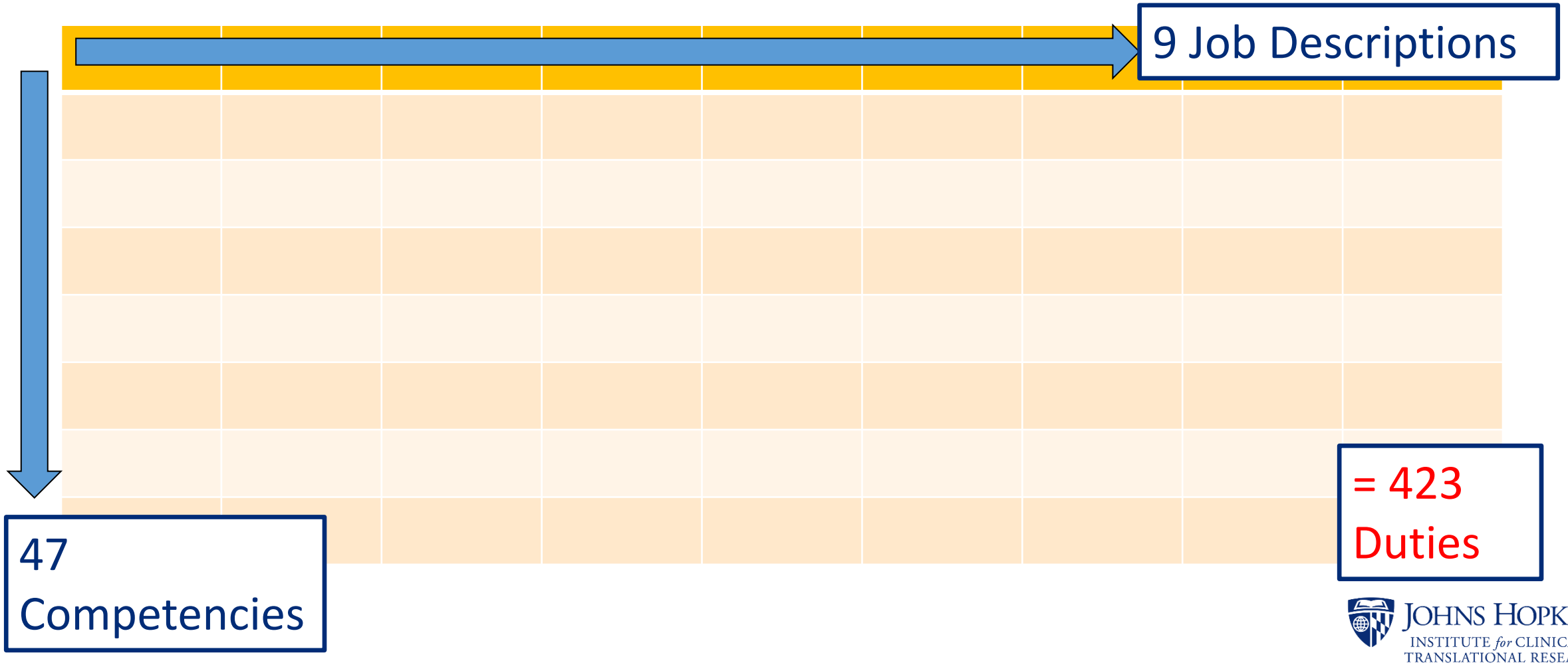
Swinging for the Fences



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Competency Grid

- Project Team met over 7 months
  - —Each member contributed equally
  - —HR Compensation viewpoint was essential
  - —Found 3 hour meetings worked best to stay engaged and on point (break as needed)
  - —Moved on if one competency became contentious or difficult
  - —Flagged some for expert follow-up (e.g., Data Management)
  - —Provided multiple updates to stakeholders along the way
  - —Presented final grid to Senior Leadership

8.1 Discuss the relationship and appropriate communication between sponsor, CRO, and clinical research site

CLINICAL RESEARCH PROGRAM ASSISTANT	CLINICAL RESEARCH PROGRAM ASSISTANT II	CLINICAL RESEARCH PROGRAM COORDINATOR	CLINICAL RESEARCH PROGRAM SUPERVISOR	SR. CLINICAL RESEARCH PROGRAM COORDINATOR	SR. CLINICAL RESEARCH PROGRAM SUPERVISOR	SR. CLINICAL RESEARCH PROGRAM COORDINATOR II	CLINICAL RESEARCH PROGRAM MANAGER	SR. CLINICAL RESEARCH PROGRAM MANAGER
Effectively communicate between a variety of entities inside (e.g., study team) and potentially **routine information** outside (e.g., CRO, Sponsor) the institution.	Same	Same **Coordinates, and actively participates in site visits.** Communicates effectively with sponsors and/or CROs if applicable	Same **Mentors lower level staff on effective communication skills**	Same **Independently coordinates, and actively participates in site visits**.	Same **Mentors lower level staff on effective communication skills**	Same Effectively communicate **complex information** between a variety of entities inside (e.g., study team) and outside (e.g., CRO, Sponsor) the institution	Same **Delegates tasks** for completion of site visits and communication with Sponsors/CROs **Trains lower level staff on effective communication skills**	Same

Special Considerations

- Each of the 9 positions had to differentiate enough to allow for advancement
- Moving from “supervision-required” to “independent”
- *Moving from “non-exempt” to “exempt”

*The key difference between exempt and non-exempt employees is that non-exempt workers are entitled to certain protections under the Fair Labor Standards Act, a federal law that sets minimum wage and overtime requirements. https://www.adp.com/resources/articles-and-insights/articles/t/the-difference-between-exempt-and-non-exempt-employees.aspx

Job Descriptions (based on grid selections)

Current JH Title: Research Program Assistant
Proposed New Title: Clinical Research Program Assistant

Summary of the position: Location, who the position reports to, campus location, hours, population, etc.

This job description does not include the left column listing the competency (see Coordinator).

Domain 1: Scientific Concepts and Research Design

Works on gaining a basic understanding of study background and rationale for the clinical study and may explain to potential participants

Domain 2: Ethical and Participant Safety Considerations

Understand the distinction between clinical care and research

Completes training required and complies with guidelines and recommendations regarding the safety, wellbeing, and rights of all participants

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Outcomes

- Project was put on hold in March 2020 (COVID-19)
- JHU used an outside contractor to validate
- Market adjustments made in 2023
- Optimized experience/education equivalency to enable advancement
- Comprehensive job family realignment underway
- Comprehensive job description revamping underway

Questions?

THANK YOU!

akeyes1@jhmi.edu

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Data Management Update: Results from Delphi

Meredith Zozus, PhD

Professor, Division Chief, Clinical Research Informatics

University of Texas (UT) Health San Antonio, Long School of Medicine, Department of Population Health Sciences

Quick Update

JTF Data Management Competencies

Meredith Nahm Zozus, PhD
Professor, Div. Chief and Director of Clinical Research Informatics
Joe R. and Teresa Lozano Long School of Medicine
University of Texas Health Science Center San Antonio

Manju Bikkanuri, MD, MS
Clinical Research Informaticist
Joe R. and Teresa Lozano Long School of Medicine
University of Texas Health Science Center San Antonio

Goal:

to update the Data Management and Informatics JTF Competencies.

Competencies are for Clinical Research Professionals such as

- Site PIs,
- Study Coordinators,
- Clinical Trial Monitors,
- Statisticians,
- Site Data Managers, …

AKA:

What every Clinical Research Professional should know about Informatics and Data Management

Status

- Team of 12 participants are participating
- Plus 2: Dr. Bikkanuri and Dr. Zozus
- Plus 2: Drs. Sonstein and Bierer

- Kick-off call held on April 18th, 2023
- Delphi Round 1, 2 and 3 completed with results in the next few slides.
- Delphi Round 4 (last round): Report circulated to the participants with Round 3 results to get their feedback.

- Plan: Review of Round 4 Report edits provided by participants. This summer.

Delphi Process Status

Round 1: Free text, "Blue Sky" input re leveled Data Management, Informatics, and Statistical competencies for Clinical Research Professionals.

Round 2: Two-dimensional rating

(1) importance of the competency regardless of the indicated level and

(2) level of agreement with the competency at each indicated level

PLUS comment fields to explain low importance and disagreement

Round 3: Round 2 slides revised to match the structure with other JTF Competencies.

Similar Two-dimensional rating as above.

Round 4: Report of JTF DM, Informatics and Statistics competencies compiled so far with Round 3 results is circulated for review for final edits. Currently at this level.

Round 5:

If significant disagreement: calls with individual participants to discuss their remaining differences and to perform additional member-checking if needed.

If minor disagreement or group is split on issues: from 1 to 3 group calls

Analysis following Round 4: group vetted draft competencies

Peer-review of results: review of the initial draft by the larger JTF. Early Fall.

Resulting Competencies

Data Management, Informatics and Statistics

Data Definition and Generation	Data Collection and Processing	Data Use	Statistical Analysis	Data Re-use

Information System Selection, Application, Use and Evaluation

Round 3 Results

Each competency statement at each level was rated on a three point Likert scale (too easy, no change, too hard).

6.1 Data definition, generation, and collection

-1	-2	1
-2	0	1
-1	0	-1

6.2 Data processing

-2	-3	0
1	-1	3
0	-1	-2

6.3 Use data to manage a study

2	-1	1
0	1	0
4	2	1
2	2	1

6.4 Statistics

1	1	0
3	1	2
1	2	1
0	0	1

6.5 Data sharing

0	0	0
0	0	0

6.6 Information systems

1	2	-3
2	1	2
0	1	-1
0	-1	0

-4	-3	-2	-1	0	1	2	3	4

Updates

No updates

Updates

Figure: 3

6.1 Ensure consistent and appropriate data definition, generation and collection for a clinical study

Fundamental	Skilled	Advanced
A.1 Describe the role of data definition, data standards, and metadata in clinical studies	B.1 Identify data to be collected from a clinical study protocol and appropriate data sources including sources of Real-World Data (RWD). Compare and contrast the appropriateness of different data sources to be informative to a clinical trial, including such things as validity of information, flexibility of implementation, and potential for impact to a therapeutic area.	C.1 Draft and maintain data element definitions for clinical studies including selection of applicable standards and metadata needed for interpretation and quality management.
A.2 Execute protocol specified procedures for observation, measurement, and recording of data	B.2 Recognize, report, and suggest remediation for deviations from data observation, measurement, and recording procedures	C.2 Select appropriate quality data generation methods and procedures; Establish and maintain systematic quality control and reporting for data generation and collection procedures
A.3 Identify the source for study data and adhere to data collection and form completion guidelines	B.3 Recognize, report, and suggest remediation for problems with data collection forms, guidelines and processes	C.3 Draft and maintain data collection processes and tools such as forms, data collection guidelines, form completion guidelines, and quality control
Example: Documents the source at the clinical investigational site for data collected in a clinical study.	**Example**: Participates in the design of a clinical study data collection form for the protocol-specified data.	**Example**: Establishes appropriate quality control procedures for critical data.

6.2 Apply best practices for processing clinical study data

Fundamental	Skilled	Advanced
A.1 Adhere to and report deviations from procedures for data processing	B.1 Identify and resolve conflicts between local and study data collection and processing procedures	C.1 Establish, maintain, and optimize data flow, workflow and related procedures for data collection, processing, privacy protections across the data lifecycle
A.2 Carry-out basic manual and computer-aided data processing such as recording, transcription, abstraction, coding, classification, derivation, entry, cleaning, transformation, linkage, and imputation. Explain the basic differences between structured and unstructured data and their impact on data use	B.2 Identify potential data problems when working with data; Use reports and information systems to identify and resolve instances of late, missing, and discrepant data; Cary-out procedures for the testing and quality control of manual and computer-aided data processing tasks	C.2 Decide when to use humans vs machines for data collection and processing activities such as conversions, calculations, data standardization, mapping, coding, classification and flagging, formatting, restructuring, record linkage and data cleaning.
A.3 Explain the role of change control in data collection and processing	B.3 Identify changes that require IRB approval and adhere to change control procedures	C.3 Assess the need for changes in data collection and processing; design, implement and evaluate changes
Example: Identifies appropriate data processing needed for clinical study data elements.	**Example**: While working with study sites, identifies and documents data flow and workflow at study sites that need to be adjusted to accommodate study-specific procedures..	**Example**: Drafts study-specific data processing procedures and ensures that documentation, whether system or human generated ensures traceability of all operations performed on data.

6.3 Interpret and use study data to manage a clinical study

Fundamental	Skilled	Advanced
A.1 Interpret basic data structures and displays such as data listings, tables, and graphical representations ; Use basic data structures and displays to detect problems and signals	B.1 Formulate and execute queries using basic logic (AND, OR, =, IN, NOT) on research databases using form-based query applications and Structured Query Language (SQL) or equivalent ; Generate simple reports for study teams using structured and unstructured data	C.1 Design, implement and evaluate use-specific information displays; Extract data contained within relational and other database systems using Structured Query Language (SQL) or equivalent
A.2 List dimensions of data quality important for a clinical study; explain the ways in which poor data quality can impact data use	B.2 Recognize instances where data problems are adversely impacting data use within a clinical study; suggest and carry-out remediation and prevention steps	C.2 Assess the impact of potential or real data quality problems on data use and analysis; design, implement and evaluate procedures and technology to prevent or detect them.
A.3 Identify and report unexpected output or performance in system automation and decision support.	B.3 Analyze study processes to suggest those that need or would benefit from automation or decision support.	C.3 Design, configure, test, implement, maintain, and evaluate information system based automation and decision support in clinical studies
A.4 Describe the basic concepts in data mining and machine learning; suggest areas where they may be useful in a clinical study	B.4 Use data mining and machine learning output and and identify potential problems in the output	C.4 Apply, implement and evaluate data mining and machine learning based tools such as text coding, natural language processing, and AI in clinical studies.
Example: Identifies study processes where alerts or reports are needed to ensure quality or optimize efficiency.	**Example**: Writes simple database queries to investigate data problems or trends.	**Example**: Designs data reports and visualizations to aid study conduct such as status reports and figures to monitor developing trends such as attrition or late visits.

6.4 Apply statistical methods and tools to design, monitor and analyze a clinical study

Fundamental	Skilled	Advanced
A.1 Calculate and communicate the importance of basic descriptive statistics including measures of central tendency, variability, and association.	B.1 Calculate and communicate specific descriptive statistics for a given data set based on its distributional properties.	C.1. Interpret more advanced descriptive statistics reflecting combinations of variables such as contingency tables, scatter plots, and regression models.
A.2 Demonstrate an understanding of basic inferential tests and their role in the scientific process.	B.2 Articulate different types of inferential tests based on the data, including comparative as well as correlational tests.	C.2 Interpret key features of inferential tests such as alpha, *p*-values, confidence intervals, and unique as compared with shared variance.
A.3 Describe the role and importance of a Statistical Analysis Plan to the integrity of a clinical trial.	B.3 Understand the relationship between a Statistical Analysis Plan and operational aspects of a clinical trial.	C.3 Identify situations when elements of the Statistical Analysis Plan are inconsistent with one another, including population definitions, sample selection, and sequencing of analyses.
A.4 Explain the importance of statistical methods and techniques to the integrity of a clinical trial**.**	B.4 Identify common threats to the validity of clinical trial such as recruiting inconsistencies, incomplete data, and insufficient power/sample size estimates that may be addressable using statistical methods and techniques.	C.4 Work effectively with a clinical trial team to respond to operational threats and issues that are sure to arise during the course of a clinical research study.
A.5 Describe the purpose, role, and scope of a Data Safety Monitoring Board in a clinical trial.	B.5 Map Data Safety Monitoring Board report recommendations to data base modifications and operations.	C.5 Ability to respond in writing to queries generated by a Data Safety Monitoring Board.
A.6. Identify criteria and types of studies needed to access evidence-based practice in the professional literature.	B.6. Evaluate and distinguish among articles in the professional literature capable of informing evidence-based practice for a specific clinical trial.	C.6. Interpret a systematic review of the literature using PICO (Problem, Intervention, Comparison, Outcomes) or other professional guidelines to frame questions relevant to evidence-based practice.
A.7 Describe the importance of a Study Design to the overall integrity of a clinical trial.	B.7 Discuss the advantages and disadvantages of adaptive study designs to a clinical trial.	C.7 Articulate key features of Innovative study designs that allow for a more efficient use resources, including but not limited to such things as stepped wedge designs, pragmatic clinical trials, and master protocols.
A.8 Explain the importance to clinical research of obtaining valid and reliable information from a clinical trial.	B.8 Distinguish between study design descriptions that do and do not meet the Design, Analyze, and Communicate (DAC) Assessment Tool (DAT) criteria.	C.8 Demonstrate facility with the Design, Analyze, and Communicate (DAC) Assessment Tool (DAT) when evaluating the potential for obtaining high quality information from a clinical trial.
Example 1A. Provide examples of descriptive statistics and what they represent in a typical data set	Example 1B. Distinguish between inferential and descriptive study results and explain how they inform or complement each other.	Example 1C. Describe what information p-values and confidence intervals in study results convey and how they are different from one another.

6.5 Follow best practices for study registration and data sharing

Fundamental	Skilled	Advanced
A.1 Describe the role of study registration, such as in Clinicaltrials.gov, in clinical research	B.1 Update and maintain records for registered studies	C.1 Use clinical study registries to support the design and planning of future studies
A.2 Explain how the FAIR principles apply to sharing data from clinical studies.	B.2 Locate and follow repository-specific specifications to curate and submit data for sharing.	C.2 Draft data sharing plans for clinical studies that ensure that data and documentation will support re-use
Example: Point-out identifiers and other metadata used to connect studies with their output such as shared data, shared resources and publications.	**Example**: Maintain a ClinicalTrials.gov record for a study.	**Example**: Identify an appropriate repository for sharing data from a publicly funded clinical study.

6.6 Leverage information systems to optimize clinical study processes

Fundamental	Skilled	Advanced
A.1 Use information systems in the conduct of clinical studies. Report unexpected systems behavior	B.1 Monitor information system used in clinical studies to identify and report unexpected systems behavior	C.1 Establish procedures and controls for information system use in clinical studies
A.2 Describe the steps in the software development lifecycle and the importance of change control	B.2 Participate in testing and change control of information systems used in clinical studies; provide training on information systems used in clinical studies	C.2 Design, configure, test, implement, maintain, and evaluate information systems used in clinical studies
A.3 Describe the purpose of and adhere to information system security procedures such as encryption and access control	B.3 Oversee local implementation of information system security procedures	C.3 Ensure that information system security procedures are appropriate
A.4 Identify instances and explain the role of system interfaces, data exchange and interoperability	B.4 Identify and report areas where interfaces, data exchange and interoperability are needed; recognize and report unexpected problems with system interfaces	C.4 Establish, implement and maintain interfaces, data exchange and interoperability for clinical studies
Example: Identify data from one information system such as an external central lab that are needed to ensure data completeness in the study database.	**Example**: Work with a study team to implement a protocol amendment that requires a change in the study data collection, i.e., a change in the data entry screens.	**Example**: Identify and write specifications for needed system interfaces for a clinical study.

MULTI-REGIONAL CLINICAL TRIALS
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JTF-P3 (Patient Partner Project) Update

Sylvia Baedorf Kassis, MPH

Program Director

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Linda Hunter, RN, MScN, PhD(C)

National Manager of the Patient and Community Partner Stream, Grant Co-Applicant

CANTRAIN

Joint Task Force for Clinical Trial Competency

Co-Creating Clinical Research Competencies to Support Effective Patient Partner Engagement Activities

Presented by:
Linda Hunter
Sylvia Baedorf Kassis

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EUPATI

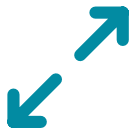
CANTRAIN

JTF - Continuing Activities

Update the Core Competency Framework based upon regulatory and technological innovation

Expand Core Competency Framework to include patient, participant, and public engagement and partnership

Provide support to individuals and organizations wishing to implement the Core Competency Framework



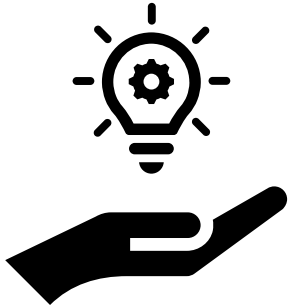
Expand the adoption and utilization of the Core Competency Framework within the Clinical Research Enterprise

JTF - The Work Ahead

Expand Core Competency Framework to include patient, participant, and public engagement and partnership

JTF Framework Addendum - Patient Partner Project (JTF-P3)

Co-Creating Clinical Research Competencies to Support Effective Patient Partner Engagement Activities



Initiative to unite a representative group of patient and caregiver partners, academic researchers and study staff, industry representatives, and others, to enhance the existing JTF Framework.

Patient Partners:

- Are individuals with lived experience of a condition, who contribute their perspectives and expertise to the research process.

- Play a critical role in shaping clinical trials to be more relevant, inclusive, and impactful.

Supporting Strong Patient Partner Relationships

Recognizing the importance of strong Patient Partner relationships, the JTF-P3 working group will focus on:

- Defining a set of competencies to maximize Patient Partners' impact as co-leaders, advisors, and reviewers of clinical research.

- Ensuring that all individuals involved in clinical research —across sponsors, sites, and other interest holders— develop the competencies needed to engage effectively with Patient Partners.

Goal and Deliverables

GOAL

To develop, by March 2026, an addendum that:

- Strengthens the skills and knowledge of **both** Patient Partners and clinical research industry professionals,

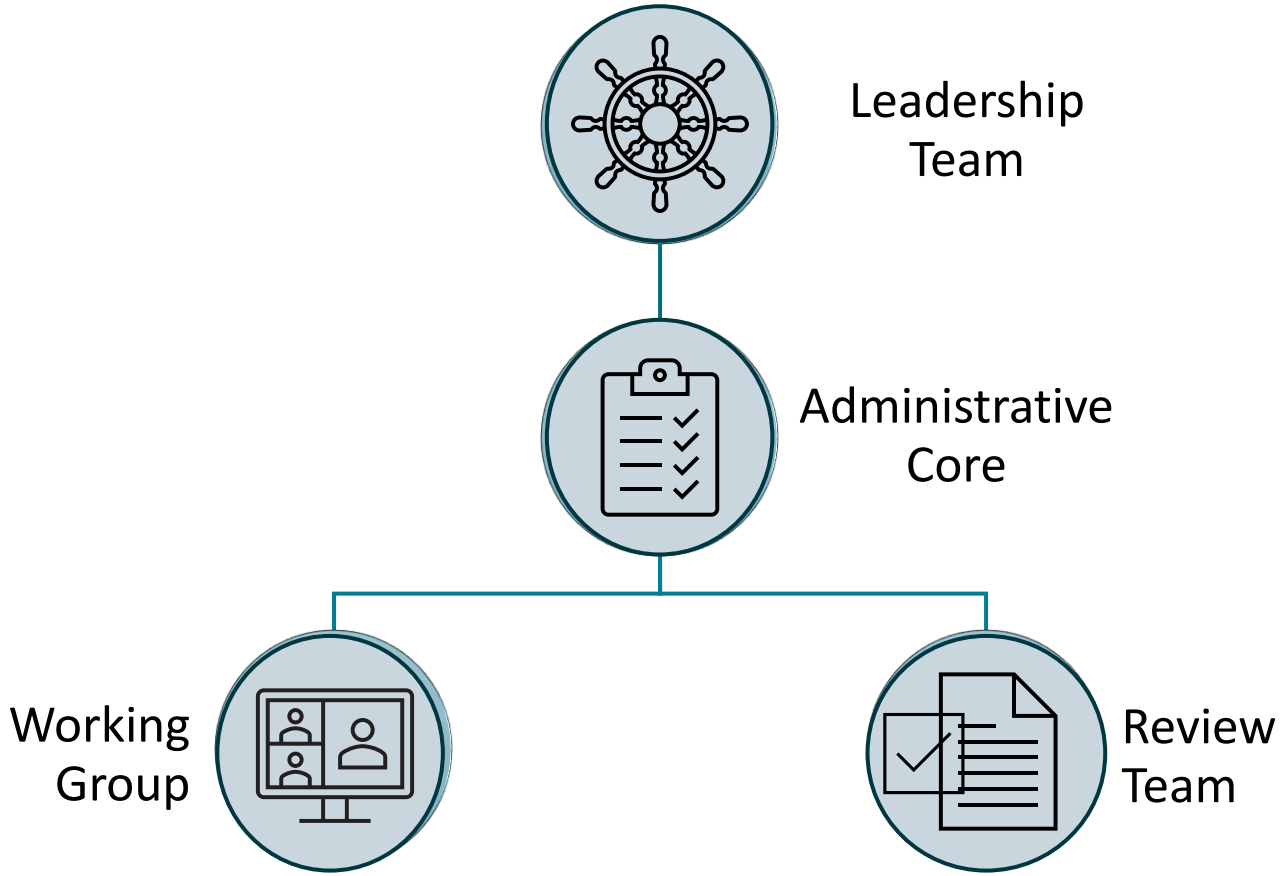
- Fosters more meaningful collaborations in clinical trials.

DELIVERABLES

- JTF-P3 Addendum

- Publication(s)

JTF-P3 Organizational Chart



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The MRCT Center is a research and policy center dedicated to improving the integrity, safety, and rigor of global clinical research.

- functions as an independent convener to bring together stakeholders from industry, academia, advocacy groups, nonprofit organizations, and regulatory agencies
- defines emerging issues in the conduct and oversight of clinical trials
- creates and implement ethical, actionable, and practical solution.

EUPATI

European Patients' Academy on Therapeutic Innovation (EUPATI), is a public-private and multi-stakeholder partnership bringing together patient organisations, academia and pharmaceutical industry.

- developed and implemented as part of the European Innovative Medicines Initiative (IMI)
- trained over 415 patient experts on medicines research and development (R&D), including clinical trials, regulatory affairs and health technology assessment
- provides training and education to thousands of learners via its open-access EUPATI Open Classroom.

CANTRAIN

The CANadian Consortium of Clinical Trial TRAINing platform (CANTRAIN), is a national training platform, dedicated to transforming how Canadians are prepared to develop, conduct, engage in, and benefit from clinical trials.

- aims to enhance clinical trial competency through an efficient training environment
- delivers cutting-edge, inclusive educational curricula tailored for students, clinical research professionals, trialists, and patient and community partners.

JTF-P3 Leadership Team and Admin Core

MRCT Center/JTF

- Barbara Bierer
- Stephen Sonstein
- Jane Perlmutter
- Carmen Aldinger
- Sylvia Baedorf Kassis

EUPATI

- Ingrid Klingmann
- Maria Dutarte

CANTRAIN

- Jean Bourbeau
- (Lisa Goos)
- Julie Dessureault
- Linda Hunter
- Sarah Ibrahim
- Mei Li

Underline – JTF-P3 administrative core
Faded – transitioning out of JTF-P3 role

Working Group

Name	Role / Org.	Country
Alan Hamilton	Consultant	Canada
Allison Dalton	GWU	USA
Annie Leblanc	SPOR	Canada
Begonya Nafria Escalera	SJD Pediatrics	Spain
Bernard Coley	Patient Partner	USA
C. Daniel Mullins	University of Maryland	USA
Christine Mungoshi	Patient Partner / Zimbabwe Brain Tumor Association	UK/ Zimbabwe
Jacquie van Ierssel	University of Ottawa	Canada
James Holahan	NYU Langone/CTSA	USA
Jana Popova	Patient Partner	Bulgaria
Janice Tufte	Patient Partner	USA
Jennifer Monaghan	Patient Partner	Canada

Name	Role / Org.	Country
Katie Bainbridge	CANTRAIN	Canada
Kaushal Shah	Arizona State University	USA
Kay Warner	GSK	UK
Kyoko Imamura	Japanese Institute for Public Engagement	Japan
Leanne Marie Hays	UCD	Ireland
Mabel Crescioni	PCORI	USA
Mandy Daly	Patient Partner	Ireland
Mitchell Silva	Patient Partner	Belgium
Monica Bógas	Roche	Portugal
Rick Bangs	Patient Partner	USA
Sandra Karabatic	Healthcare Provider	Croatia
Sara Riggare	Patient Partner	Sweden
Trudy Flynn	Patient Partner	Canada

Review Group

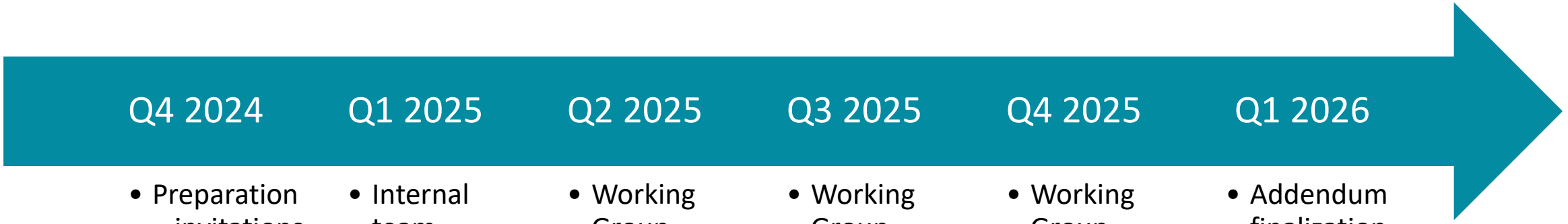
Recruiting international, representative individuals from different areas of expertise.

The review team will be asked to participate in ~4-5 meetings and engage in periodic reviews of project materials.

We expect an orientation meeting to take place in July/August 2025 and for the work to be most active in September 2025-March 2026.

An expected commitment of ~8 hours of review time and ~5 hours of meeting time.

High Level Timeline – approximately 15 months



Q4 2024	Q1 2025	Q2 2025	Q3 2025	Q4 2025	Q1 2026
• Preparation – invitations out (Dec) • Internal team building	• Internal team building cont'd • Launch Working Group (Jan-Feb) • Workgroup Activities - start	• Working Group Activities • Review Team engaged	• Working Group Activities • Strategic Review Team involvement • Intro Webinar?	• Working Group Wraps Up • Review Team Final Input	• Addendum finalization • Release (with joint webinar) • Draft paper and prep for submission

e.g. scoping, gap analysis, competency additions/updates

Key Milestones and Activities To Date

- The JTF-P3 Working Group activities began in March 2025.
- Informed by agreed-upon Guiding Principles and Collaboration Expectations
    - Inclusivity & Equity
    - Co-creation & Shared Leadership
    - Transparency & Accountability
    - Evidence-informed & Practice-driven
    - Cultural and Global Relevance
    - Ethics & Integrity
    - Agility & Focus

Key Milestones and Activities To Date

- Completed a review of existing relevant and related resources

- Compiled a focused list of resulting themes

    - Diversity and Representation
    - Cultural Safety/Humility/Sensitivity and Unconscious Bias
    - Knowledge, Skills, and Attitudes
    - Evaluation

- Divided thematic foci into breakout group assignments

    1) Review Existing JTF

    2) Review already drafted additions

    3) Consider New Competency Domain Areas

Looking Ahead

- Review Team Outreach

- Addendum Alignment, Validation, and Approval

Conclusions/Key Takeaways

A Patient Partner focus was identified as a need from diverse sources.

This initiative is patient-driven, collaborative, and an exercise in co-creation.

Tangible outcomes and deliverables are expected, further elevating the Patient Voice and contributing to a clinical research culture that prioritizes Patient Partner inclusion.

Questions?

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Discussion

Barbara Bierer, MD
Faculty Director, MRCT Center
Co-Chair, JTF
Stephen Sonstein, PhD
Co-Chair, JTF

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Thank you!

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