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

10 December 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 and to potentially make some or all of the recording available for on-demand viewing.

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

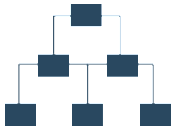
Knowledge of how drugs, devices, and biologicals are developed and regulated

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

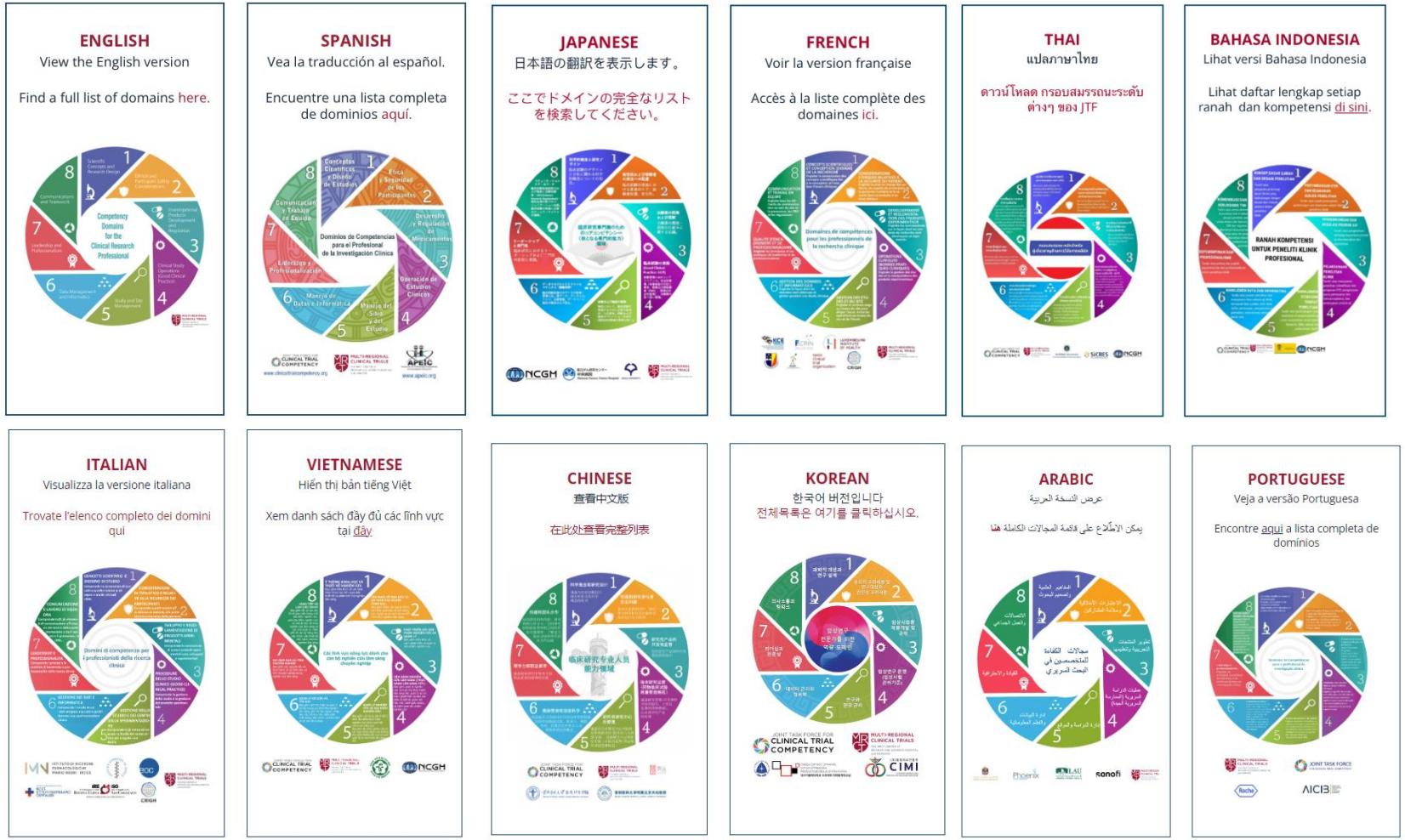
Competencies are reflected at a Basic, Skilled, and Advanced level

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 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
1:00-1:10 PM EST	Welcome and Introduction	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center **Stephen Sonstein, PhD** Co-Chair, JTF Consultant, MRCT Center
1:10-1:30 PM EST	From Translation to Transformation: Advancing Clinical Research Competencies in Pakistan through the Urdu JTF framework	**Saboora Waris, PhD and Post Doc (Australia), ACRP-CPI, IPPCR, QMS Lead Auditor (9001:2015)** Director Research and Quality Maroof International Hospital **Baber Saeed Khan, MBBS, MPH, CPI, FAPCR** Director Clinical Trial Unit National University of Medical Sciences
1:30-1:50 PM EST	Designing Experiential Learning with a focus on JTF Competencies: The Clinical Research Sciences Program Internship at North Carolina Central University	**Tracie Locklear, PhD** Research Assistant Professor Lead, Clinical Research Sciences North Carolina Central University

Agenda (cont.)

Time EST	Topic	Speaker / Facilitator
1:50-2:10 PM EST	Designing an M.S. Program in Clinical Data Science using JTF Competencies	**Richard Ittenbach, PhD** Clinical Data Science Program, Director Division of Biostatistics and Epidemiology, Professor University of Cincinnati College of Medicine
2:10-2:30 PM EST	Professional Development of the Clinical Research Workforce in New Zealand	**Raulle Sol Cruz** Research Manager Research Office & Clinical Trials Unit | Capital, Coast and Hutt Valley Health New Zealand Research | Evidence & Pathways
2:30-2:50 PM EST	Advancing Professional Standards and Recognition for Australian Clinical Trial Professionals	**Tim Boyle, PhD, MChMPP** Chief Executive Officer ARCS Australia
2:50-3:00 PM EST	Discussion and Wrap-up	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center **Stephen Sonstein, PhD** Co-Chair, JTF Consultant, MRCT Center

Next JTF Biannual Global Meeting

Monday, 15 June 2026, 9:00-11:00 AM EDT

To register:

https://lp.constantcontactpages.com/ev/reg/t5hg7mt/lp/ad346be2-437e-4fe0-943b-8ecc2d8d1837

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

NUMS
NATIONAL UNIVERSITY OF MEDICAL SCIENCES

From Translation To Transformation

Advancing Clinical Research Competencies In Pakistan Through The Urdu JTF Framework

[Video Recording]

Joint Task Force For Clinical Trial Competency (JTF)

Biannual Global Meeting 2025

Dr. Saboora Waris, PhD and Post Doc (Australia),
ACRP-CPI, IPPCR, QMS Lead Auditor (9001:2015)
Director Research and Quality
Maroof International Hospital

NCCentral UNIVERSITY

Designing Experiential Learning with a focus on JTF Competencies: The Clinical Research Sciences Program Internship at NCCU

Tracie Locklear, PhD
Research Assistant Professor
December 10, 2025

About Our Program

- The Clinical Research Sciences Program (CRSP) was established in the Fall of 2018 and launched in Spring 2020
- Asynchronous/online, hybrid, and face-to-face, to support various learning needs and meet the challenges of a busy life.
- Three unique offerings: (1) a Bachelor of Science in Clinical Research; (2) a minor; and (3) a post-baccalaureate certificate in Clinical Research.
- Instructors are clinical research professionals from various backgrounds with a combined 25 years of experience.

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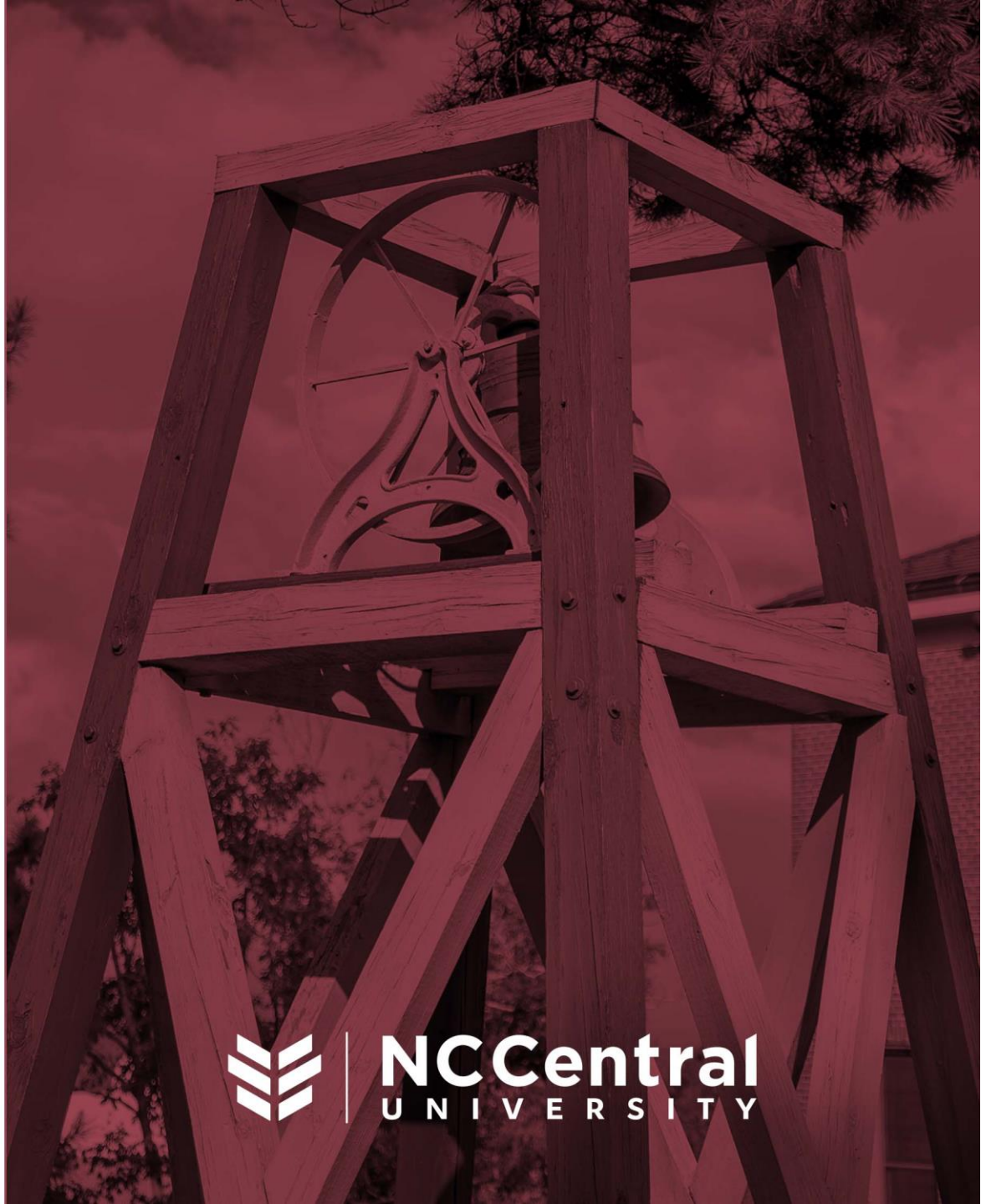
Bachelor of Science in Clinical Research Degree

Course Title	Credits
Principles of Clinical Research	3
Pharmaceutical Data Science/Biostatistics	3
Clinical Biostatistics	3
Clinical Trial Management I	3
Clinical Trial Management II	3
Clinical Biochemistry	3
Pharmacology	3
Regulatory Sciences	3
Pathophysiology	3
Pharm Tech Writing	3
Medical Bioethics	3
Pharmacovigilance	3
Advanced Data Management	3
Medical Terminology (online)	2
Presentation Skills	1
Literature Review	1
Interpersonal Skills	1
Clinical Trial Protocol Design	1
BioBanking & Interpreting Lab Data	1
Good Clinical Practice	1
Clinical Research Internship	12



Aligning Objectives

- Align objectives with JTF competencies
- Scaffold across program curriculum
  - ➢ Freshman-Sophomore (Fundamental)
  - ➢ Junior-Senior (Skilled)

Domain 2: Ethical and Participant Safety Considerations

Fundamental: Recognize difference between clinical equipoise and therapeutic misconception

Skilled: Explain rationale and demonstrate how these concepts impact patient understanding

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

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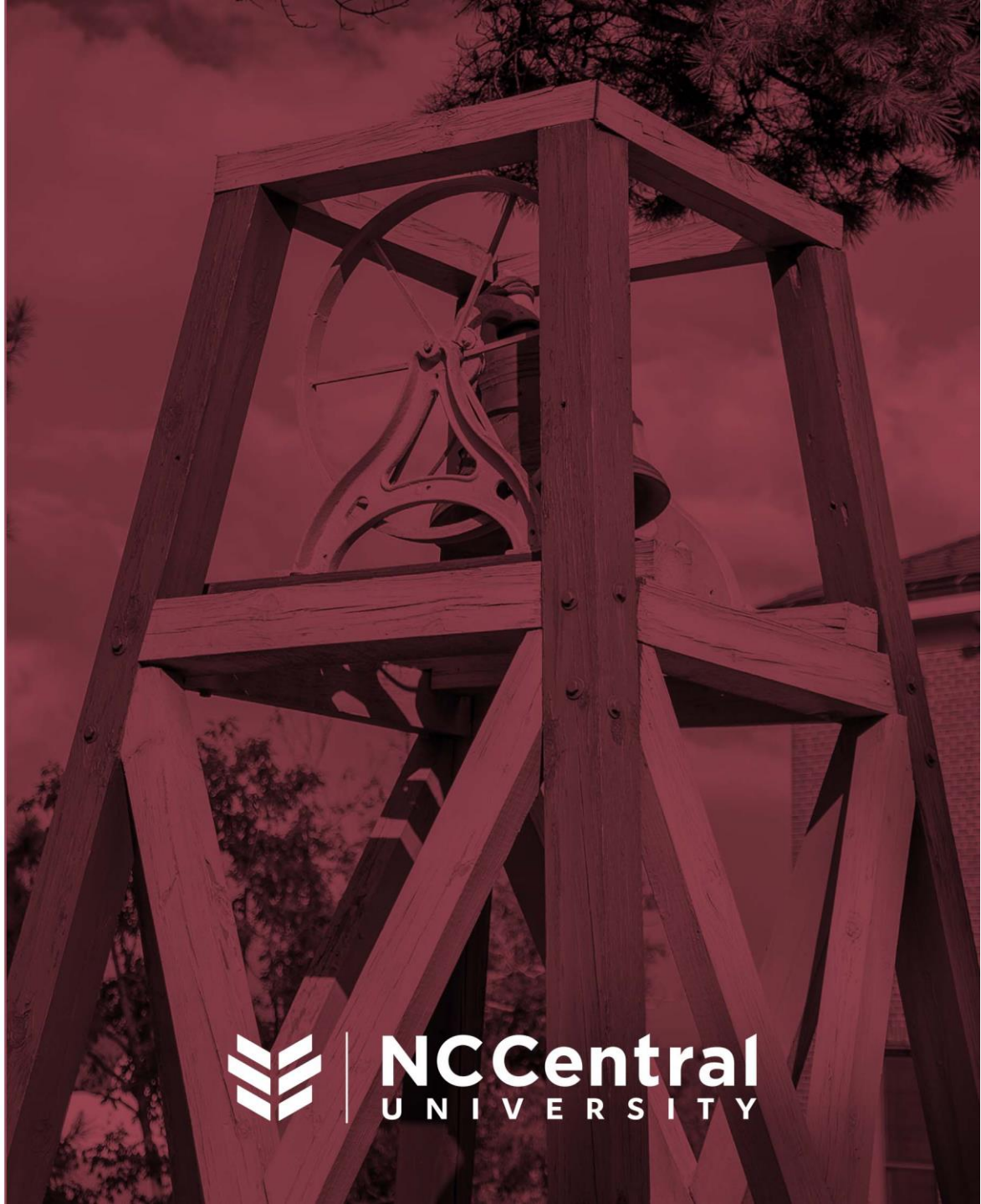
Setting and Evaluating Objectives

We focus on how students learn BEST!

- Students come with prior knowledge and life experiences
- Create opportunities for students to display personal strengths
  - **8 Intelligences** (linguistic, logical-mathematical, spatial, bodily-kinesthetic, musical, interpersonal, intrapersonal, naturalist)
  - A variety of assessments improve outcome quality (e.g., video presentation vs. written essay/poem)



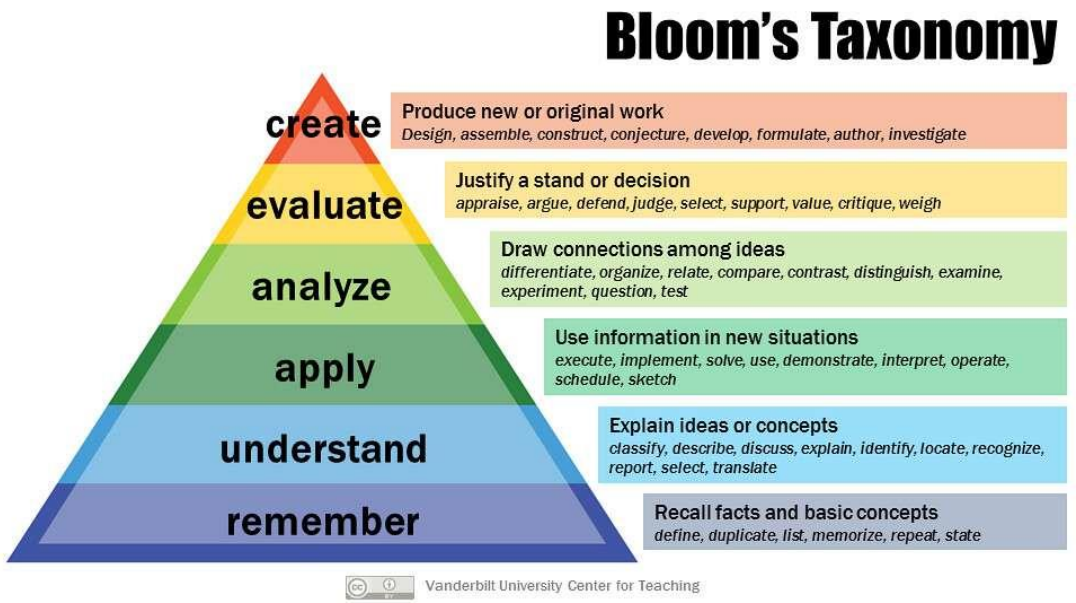
Howard Gardner. Frames of Mind: The Theory of Multiple Intelligences. (1983)

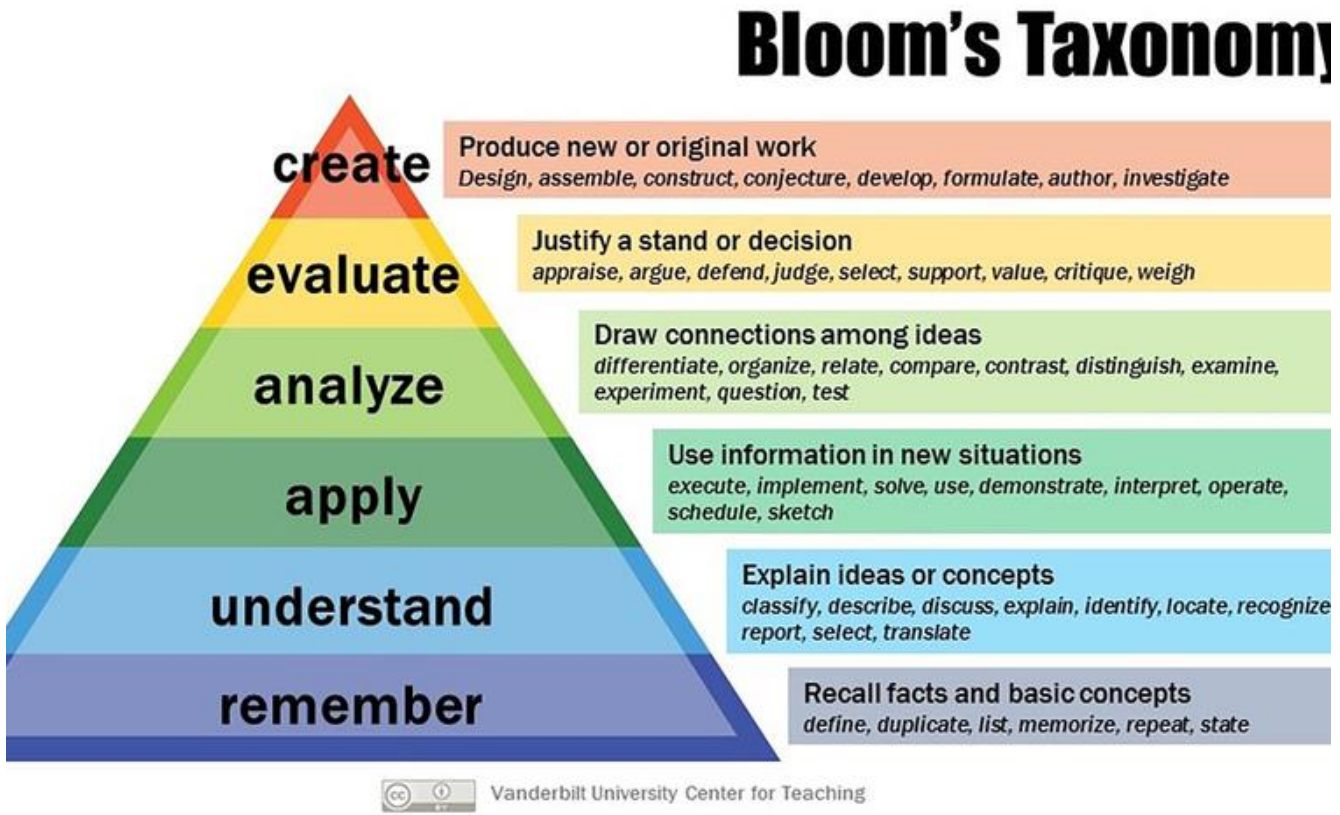
Using A Trusted Educational Framework

The Bloom's Taxonomy

Tiered framework for developing learning objectives

Higher-order learning objectives and assessment to evaluate knowledge, as students develop





Aligning Competencies with Learning Objectives

Strategically aligning the fundamental and skilled level competencies with Bloom's Taxonomy

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Image credit: https://cft.vanderbilt.edu/guides-sub-pages/blooms-taxonomy/

Internship Course Details

- Students enroll in the CRSB 4000 course for academic credit (12 credits)
- 15 weeks
- Unpaid
- Part-time (minimum of 12 hours/week and max. 30 hours/week)
- Can be on-site, fully remote, or hybrid
- Students are matched based on interests and availability
- Requires background check, drug screen, interview
- NCCU provides stipend and liability insurance for student

Learning Objectives for Interns

- **APPLY** Good Clinical Practices in the conduct of clinical research
- **[Understand]** Execute the role/responsibility of an entry-level clinical research professional within the clinical research team
- **APPLY** professionalism and interpersonal skills to ensure success in clinical and scientific workplaces
- **[ANALYZE]** Demonstrate qualitative or quantitative data collection and analysis research skills
- **[EVALUATE]** Apply literature review skills to develop and share new knowledge in clinical and scientific research workplace
- **[CREATE]** Execute well-researched presentations with confidence

Examples of Internship Activities

- Creating newsletters, social media posts, educational materials for research studies
- Conducting literature reviews and summaries on a specific research topic
- Assist with document preparation, review, and IRB/IEB submissions
- Attend meetings and take meeting notes
- Observe/practice patient recruitment and follow up data collection
- Building databases (e.g., RedCap)
- Data management and analysis

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Community Engagement Objectives

- Participate in community outreach to improve education on clinical research/clinical trial participation in underrepresented communities
- Utilizing RCMI infrastructure to support community engagement activities (e.g., food, give-aways, community connections, etc.)
- Assist with community outreach initiatives, provide clinical research education, Q/A, mobile unit tour, and providing free health assessments

Evaluating Knowledge

- **APPLY** Good Clinical Practices in the conduct of clinical research
- **UNDERSTAND** and describe the roles of various clinical research professionals within the clinical research team
- **APPLY** professionalism and interpersonal skills to ensure success in clinical and scientific workplaces
- **[ANALYZE]** Build skillsets in quantitative research
- **[EVALUATE]** Apply literature review skills to develop and share new knowledge in clinical and scientific research workplace
- **[CREATE]** Execute well-researched presentations with confidence

- Assessing adherence to study protocol and regulations via preceptor feedback
- Assessing journal and discussion board entries
- Assessing dress code and attendance policy adherence; verbal and written communication adherence
- Assess data collection and interpretation skills via visual presentation

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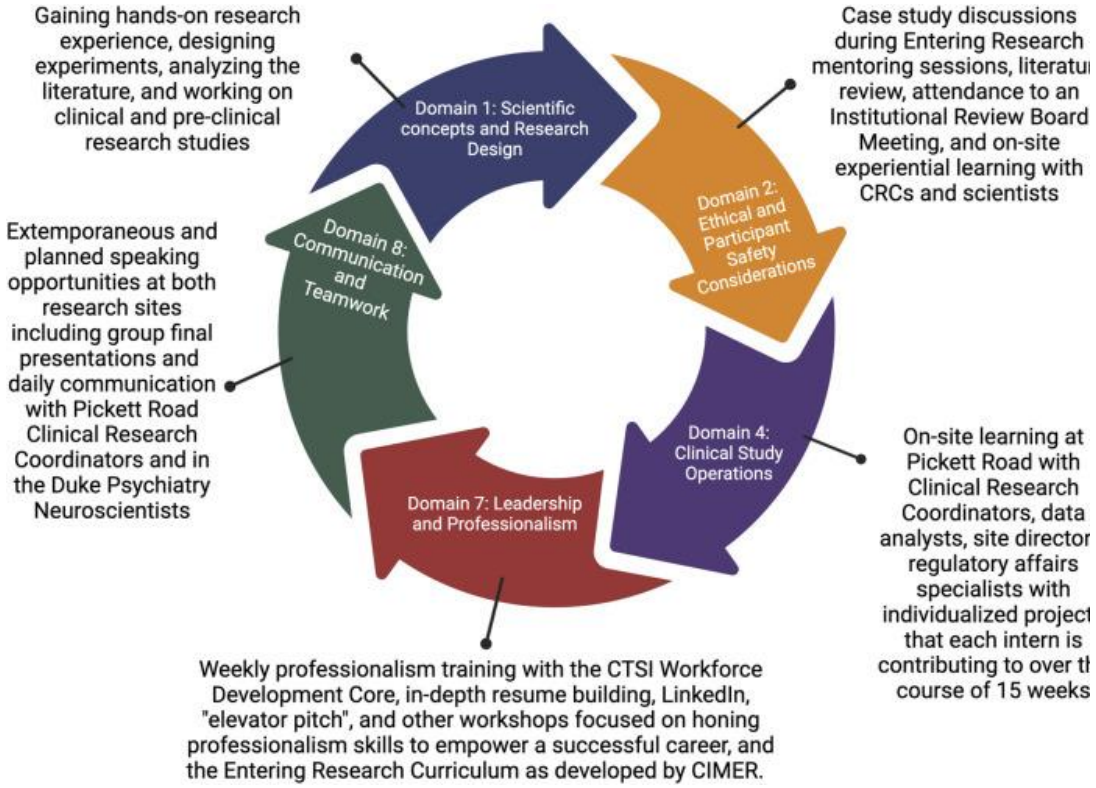
Image credit: https://cft.vanderbilt.edu/guides-sub-pages/blooms-taxonomy/

Publications



› Front Pharmacol. 2023 Dec 6:14:1294535. doi: 10.3389/fphar.2023.1294535. eCollection 2023.

A novel cross-institutional college internship program to train future diverse leaders in clinical research with data-driven approaches to assess impact

Julia Derk [1 2 3], Kafui Dzirasa [1 2 3 4], Tracie Locklear [2 5]

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Next Steps: Assessing Student Feedback

- 9 students have gone through the internship to date
- IRB protocol in place to collect pre and post internship feedback
  - Self-efficacy
  - Feelings of belonging
  - Access to research opportunities
  - Mentor-Mentee relationship
  - Future education and career goals

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Where Purpose Takes Flight

For more information please contact:

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Building for the Future:

Designing an M.S. Program in Clinical Data Science using JTF Competencies

Rick Ittenbach, PhD
Clinical Data Science Program, Director
Division of Biostatistics and Epidemiology, Professor
Cincinnati Children's Hospital and
University of Cincinnati College of Medicine

Joint Task Force for Clinical Trial Competency
Biannual Global Meeting
December 10, 2025 (virtual)

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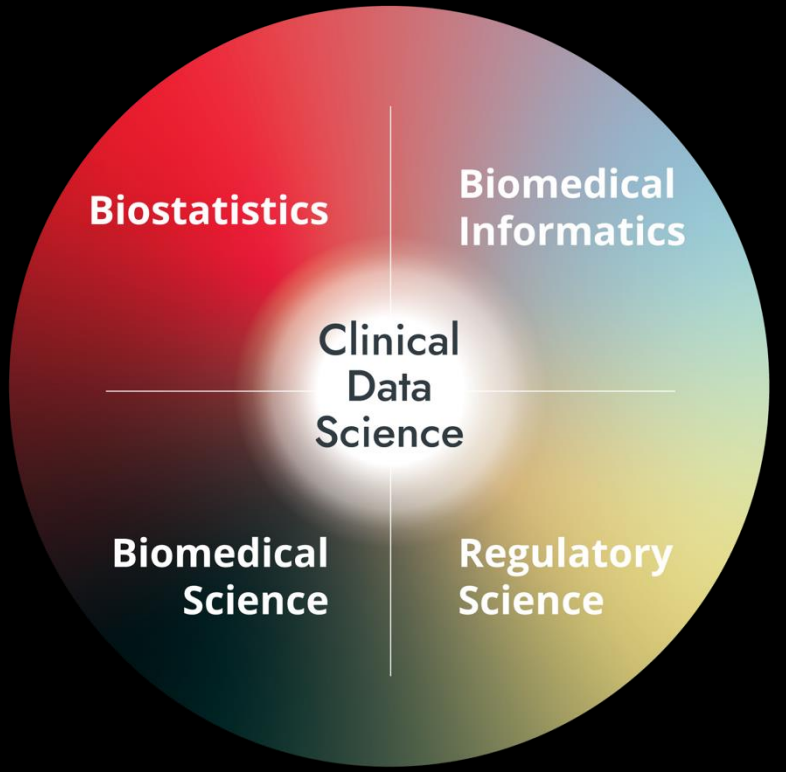
Purpose

To provide a graduate-level curriculum in clinical data science, devoted to the measurement, acquisition, care, treatment, analysis, and inferencing of clinical research data

Intended outcomes

- Prepare students for work in academic, industry, and government research settings
- Provide a unifying knowledge base for the profession



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First Principles

- Clinical Data Management/Science was a job class mandated by Congress [1-3]
- Born and nurtured in industry
- Field has advanced but the education and training have not [4]

- Content reflective of underlying knowledge base
    - Complex disciplines = *f*(complex, often hybridized skill sets)
    - Translational science are more hybridized than ever before
    - Operational and regulatory constraints
- Nontransparent and diffuse labor market wrt educational programs

- Dedicated, structured learning model is crucial for scientific learning today

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Rationale

How are CDM/S' prepared for such an important role? [4]

- No formal educational programs in *Clinical* Data Science
- Rebranded statistics/computer science programs
- Employer-based training programs
- Professional short courses (e.g., JSM, AMIA, DIA, SCDM, SOCRA)
- Online learning platforms (e.g., Coursera, DataCamp, edX, Udemy)
- Generic clinical research programs

Population Profile (as of July 29, 2025) [5]

- Clinical Data Scientist = Clinical Data Manager (USDoL 15-2051.02)
- Employment : 202,900 professionals today (growth rate of 9% agr 2023-2033)
- Median U.S. salary : $112,600 (TN $104,790; NJ $130,570)
- Education : 85% BA/BS, 5% AS, 10% other
- Spec Vocational Prep : 7 to 8 (extensive experience, 2 to 10 years)
- Worldwide need [6-9]

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Data Scientist Professional Skill Areas

Clinical Data Science Courses: University of Cincinnati

Scientific Understanding	Articulate in sufficient detail, in oral as well as written forms, the sequence of steps in a clinical research study as they relate to the scientific method, from initial study design and setup through database lock and closeout.
Knowledge and Management of Research Data	Design, monitor, and manage the flow of data through the lifecycle of a clinical research study using multiple data types.
Regulatory Science	Demonstrate understanding of and familiarity with key regulatory guidelines needed to ensure that clinical research complies with all local and federal policies, laws, and regulations.
Leadership	Demonstrate essential leadership skills needed for practice as a clinical data scientist in a team science setting.
Professional Communication	Present project work, oral as well as written, in a professional and scientifically rigorous manner.

5 Thematic Areas (Core Competencies)

- Premise students' learning on science and the scientific method
- Focus on data operations within the science of biomedical research
- Address contemporary needs within clinical research today:
  - regulatory science
  - leadership fundamentals
  - professional communication

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National Center for Education Statistics Classification of Instructional Programs

Data Science, General, 30.7001

. . . the interdisciplinary perspectives of applied statistics, computer science, data storage, data representation, data modelling. Includes programming, data management . . . information retrieval, mathematical modeling, . . ., visual analytics

Data Science, Other, 30.7099

any program not listed above s.a. data science, analytics, health data science, biostatistics

Source: https://nces.ed.gov/ipeds/cipcode/cipdetail.aspx?y=56&cipid=92953

Curriculum and Schedule

Proposed Clinical Data Science Program		12m Program			24m Program					
Course Title	Course Number	Fall	Spring	Sum	Fall 1	Spr 1	Sum 1	Fall 2	Spr 2	Sum 2
Core Courses										
Clinical Data Science I: Overview [a]	CDS 6010	📖			📖					
Clinical Data Science II: Roles & Responsibilities [a]	CDS 6020	📖					📖			
Clinical Data Science III: Design & Implementation [a]	CDS 6030		📖						📖	
Clinical Data Science IV: Practicum (6 hr) [b]	CDS 6050			📖						📖
Research Courses										
Biostatistics in Clinical Data Science [a]	CDS 7000	📖			📖					
Introduction to Medical Informatics [a]	CS, BMIN 7053	📖						📖		
Introduction to Biomedical Science [a]	CDS 7020		📖			📖				
Clinical Research Regulatory Overview [b]	BE 7036		🕮			🕮				
or Global Regulatory Drugs/Devices [c]	PHDD 8010									
Clinical Research Ethics [a]	PHIL 6050		📖				📖		📖	
Elective Course(s) (course options listed below)										
Total Credit Hours		12	15	6	6	6	6	3	6	6

Note. [a] on ground, in person; [b] online synchronous; [c] online asynchronous; 🕮 recommended placement in the program; ♦ when electives are offered.

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Methodology

Procedures

1) Theoretical framework
2) Ordered sequence of core courses (knowledge base)
3) Required research courses
4) Listing of electives
5) Pervasive skills and evaluation plan

Quality Assurance

Phase I : Mapping of course content to professional core competencies [10-13]
Phase II : Course syllabi shared with (a) local experts, (b) regional/ national experts, and then (c) international advisory board

Methodology (cont'd)

Joint Task Force for Clinical Trial Competency Draft Date: 28 Oct 25	CDS 6010	CDS 6020	CDS 6030	CDS 6050	BE 7036	PHDD 8010	CDS 7000	CDS 7020	CS 7053	PHIL 6050
Scientific Concepts and Research Design (Domain 1)										
Apply principles of biomedical science to investigational product discovery and development and health related behavioral interventions.(1.1)	w 1	w1	w1	w2	w2			w1		
Identify scientific questions that are potentially testable clinical research hypotheses. (1.2)	w 2		w2	w2			w2-4,6,7			
Identify the elements and explain the principles and processes of designing a clinical study. (1.3)	w 11		w2	W2	w2		w 13			
Maintain awareness of new technologies, methodologies and techniques which enhance the conduct, safety and validity of the clinical study. (1.4)	w 12	w6	w8,13		w 5,9,13	w10,12	w6,7,13, 14	w14,15	w1,3,8-14	w11
Critically analyze clinical study results. (1.5)	w 11									
Data Management and Informatics (Domain 6)										
Describe the role and importance of statistics and informatics in clinical studies. (6.1)				w4			w1		w1	
Describe the origin, flow, and management of data through a clinical study. (6.2)	w 5,6	w4,5	w15	w4	w5,9,15	w2,3				
Describe the best practices and resources required for standardizing data a collection, capture, management, analysis, and reporting. (6.3)	w 10	w2,3		w4	w5,9					
Describe, develop, and implement processes for data quality assurance. (6.4)		w7			w5					

Methodology (cont'd)

Mapping of ASA DSP Skills Areas to CDS Courses
Draft Date: 30 Jul 25

	Core Courses				Research Courses				
	CDS 6010	CDS 6020	CDS 6030	CDS 6050	BE 7036	CDS 7000	CDS 7020	CS 7053	PHIL 6050
Data Privacy and Stewardship									
Ensuring protection of personal and sensitive data	w10							w2,3,8	w11
Managing loss of sensitive data		w 6, 12-13		w6	w8				
Data stewardship and standards	w10, 12							w7	
Definition, Acquisition, Engineering, Architecture, Storage and Curation									
Data collection and management	w2-8	w2-4		w4				w2-4	
Data engineering	w7-8	w7	w8	w4	w4	w9-10		w5	
Deployment			w12-14						
Problem Definition and Communication with Stakeholders									
Problem definition			w1		w2				
Relationship management	w15		w15	w8	w16			w15-16	w15
Problem Solving, Analysis, Statistical Modeling, Visualization									
Identifying and applying technical solutions and project management		w10-11	w3-4			w2-4			
Data preparation and feature modeling	w12					w9-11		w6,8,9	
Data analysis and modeling building		w9	w13-14			w12-14			
Evaluation and Reflection									
Project evaluation		w9		w8				w5-6	
Ethical behavior					w1			w7	w1-12
Sustainability and best practices	w1			w2					
Reflective practice and ongoing development	w15	w15	w15	post prac					

Note . w = week of the semester the course is taught.

Data Scientist Professional Skill Areas

Executive Education: University of Cincinnati

Day 1	Day 2	Day 3	Day 4	Day 5
Breakfast				
Opening Session	News and Notes	News and Notes	News and Notes	News and Notes
Clinical Data Science I: Overview*	Clinical Data Science II: Roles & Responsibilities*	Clinical Data Science III: Design & Implementation*	Clinical Data Science IV: Field Placements	Good Clinical Practice Good Clinical Data Management Practices
Challenging Case Study	Critical Thinking	Challenging Case Study	Communication	Challenging Case Study
Lunch				
Biomedical Informatics	Biostatistics	Biomedical Science	Regulatory Science	Clinical Research Ethics
Leadership	Challenging Case Study	Team Science	Challenging Case Study	Closing Session
Class Dinner with Invited Speaker	Dinner on Own	Class Dinner with Invited Speaker	Class Reception and Dinner in Community	

Note . * Denotes core content.

Source: Ittenbach et al. *J Clin & Trans Sci*, in press

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Clinical Data Science Curriculum Key Attributes

- Provides students with a toolbox of skills and context for practice
- Coursework defines the knowledge base for the new discipline
  - Identifies it as a technical, biomedical specialty
  - Draws from but does not duplicate foundational knowledge

- Formal sanctioning of the profession among academic medical centers
- Built on established principles of educational theory and practice
- Content mapped to core competencies of professional societies
- Clinical research ethics (reqd) project mgmnt (elective) elevate the program
- Required practicum at leading research organizations

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Further Reading

CTS Clinical and Translational Science

Open Access

TUTORIAL | Open Access

From Clinical Data Management to Clinical Data Scie for a New Educational Model

Richard F. Ittenbach

Source: Ittenbach, R. 2023. *Clinical & Transl Sci, 16 (8), 1340-1351*

4

Journal of the Society for Clinical Data Management

Ittenbach RF, Neubauer A, Cameron S. Internships in Clinical Data Science: A Brief Report. *Journal of the Society for Clinical Data Management*. 2024; 4(1): 4, pp.1–5. DOI: https://doi.org/10.47912/jscdm.316

EDUCATION AND PROFESSIONAL DEVELOPMENT

Internships in Clinical Data Science: A Brief Report

Richard F. Ittenbach*, Amy Neubauer† and Stephen Cameron‡

14

Empowering professionals: An intensive short course on fundamentals of clinical data science

Richard F. Ittenbach[1], Brian McCourt[2] and Maurizio Macaluso[1]

[1]Division of Biostatistics and Epidemiology, Cincinnati Children's Hospital, University of Cincinnati College of Medicine, Cincinnati, OH, USA and [2]Duke Clinical Research Institute, Duke University, Durham, NC, USA

15

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Thank you

Questions/Correspondence:
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11 DECEMBER 2025

PROFESSIONAL DEVELOPMENT OF THE CLINICAL RESEARCH WORKFORCE IN NEW ZEALAND

A Joint Task Force-aligned National Workforce Study in a Reformed Health System

Raulle Sol Cruz

Research Manager

Doctoral Candidate

Academic and Professional Journey

Business Administration and Management

Bachelor of Science in Nursing

ICU Nurse – Philippines

Master of Arts in Nursing

ICU Nurse - New Zealand

Flight Nurse

Patient-at-Risk Nurse

Research Nurse

Project Manager

ICU Clinical Trials

ICU Research Manager

Research Manager - CCHV

Professional Doctorate in Health

The Aotearoa New Zealand Context

National Public Health System

High Quality, Globally Aligned Standards

Diverse Population and Research Strengths

A Strong Cultural Lens: Māori Values in Research

New Zealand and Clinical Trials

~ 4,993,923

NZ population

European ~68%

Maori ~17.8

Asian ~17.3

Pasifika ~8.9

Source – Stats NZ 2023

2,485

clinical trials

> 1.6 million participants

Registered in Clinicaltrials.gov and ANZCTR 2006-2015

Top 5 globally

(Population ≥1 million) for registered interventional clinical trials per million population, 2009–2022

Bjerg et al (2025)

$150 million per year

Economic contribution of clinical trials of new medicines, 2013-2018

NZIER (2020)

NZ Health Strategy

1. **Voice at the heart of the system**: Recognising and responding to the voices of our people and communities throughout the health system, so people have greater control over the design of services and decisions made about their care.
2. **Flexible, appropriate care**: Developing services that are focused on preventing illness and delivering care closer to home, and support access for the most under-served communities.
3. **Valuing our health workforce**: Recognising our health workforce as our most valuable asset and key to achieving transformative change. Supporting the health workforce to develop the diverse, skilled and confident workers of the future.
4. **A learning culture**: Creating a culture of continuous learning and improvement that supports high quality, innovation, research and evaluation.
5. **A resilient and sustainable system**: Ensuring preparedness for future shocks and the best use of resources to manage demand for health services and affordability of the system over the long-term.
6. **Partnerships for health and wellbeing**: Working with other sectors and across government to partner on actions that address the drivers of health and wellbeing and support healthy communities and environments.

Clinical Trials Workforce: What we know and the gaps we must address

Complexity is rising faster than capacity

Burnout and turnover are now universal pain points

Growing activity, but a fragile and uneven workforce

No national pathway for training, roles, or progression

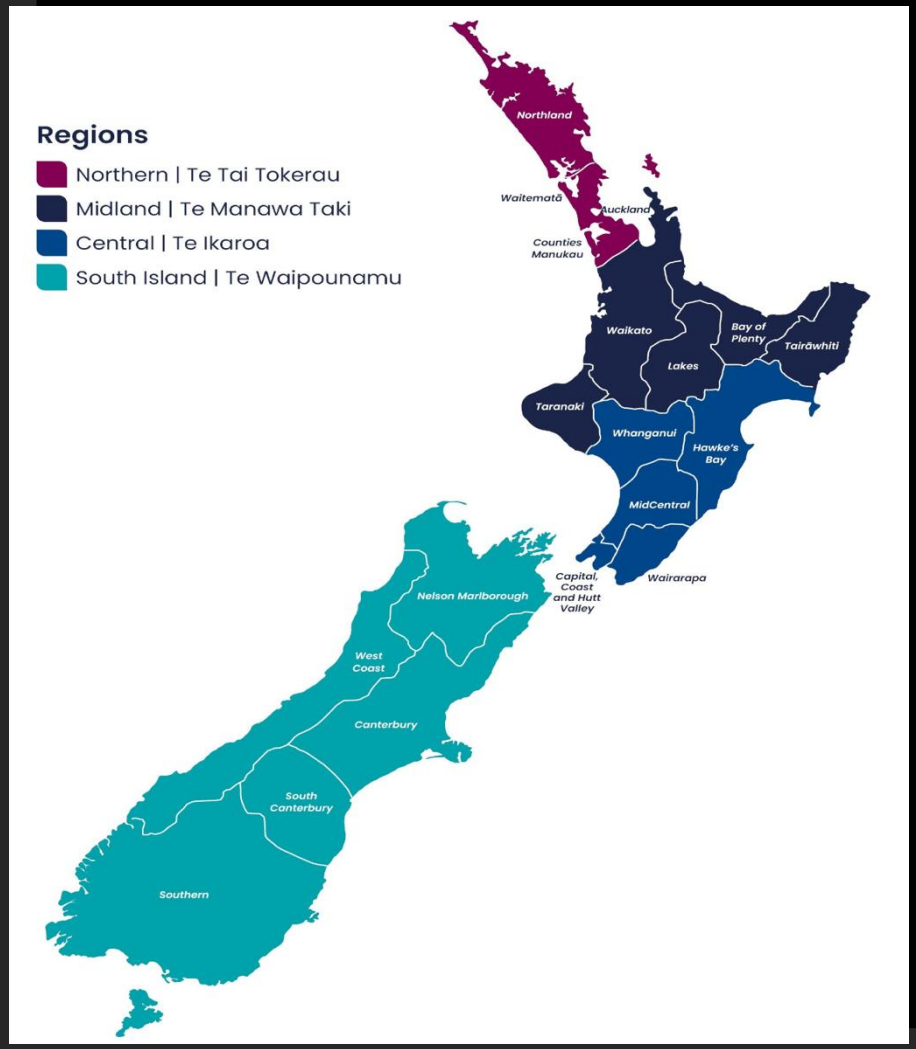
The actual size, skills mix, and PD needs of our workforce

How existing PD activities influence job satisfaction and retention

Research Question

What are the professional development needs of Clinical Research Coordinators (CRCs) conducting clinical trials in NZ public hospitals and how do the existing professional development activities impact job satisfaction and retention?

Why this matters and why now?



01

New Zealand’s health system has undergone a major structural reform

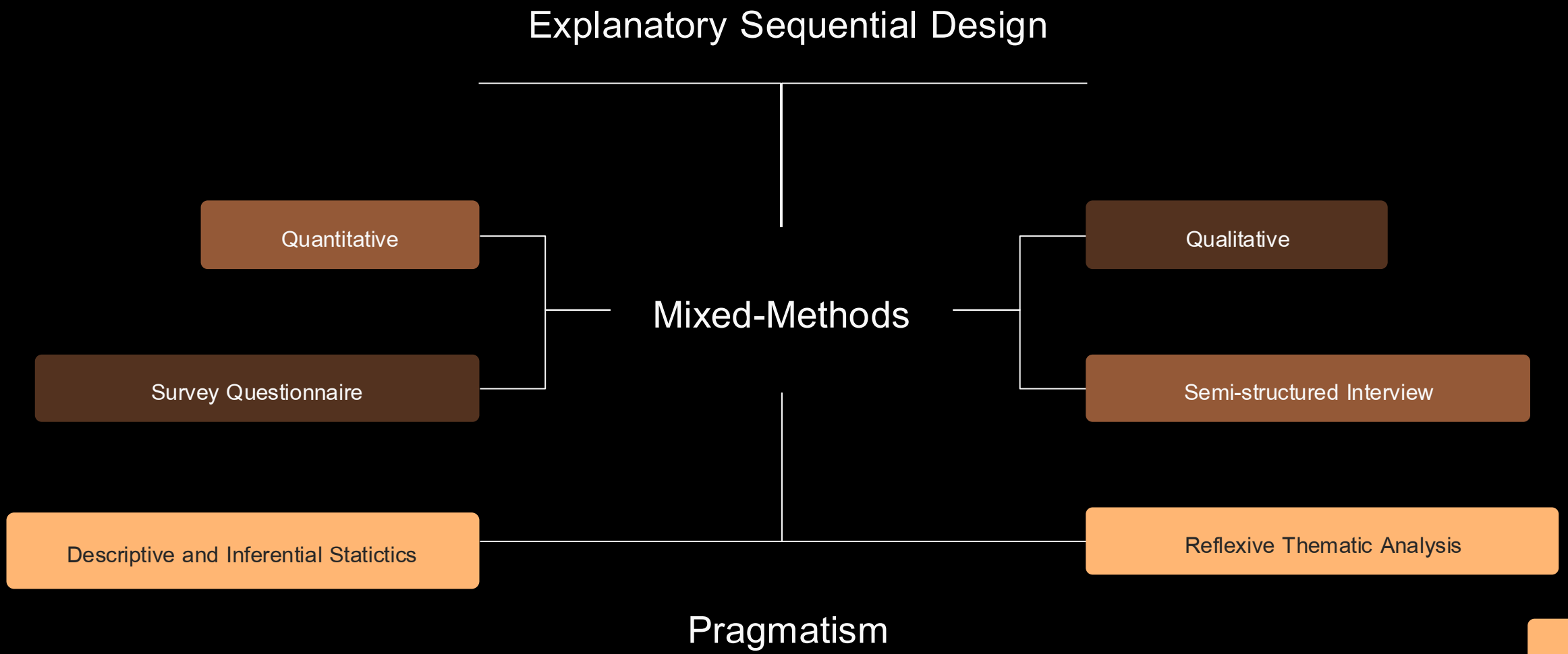
02

Growing Trial Complexity Requires a Skilled, Supported Workforce

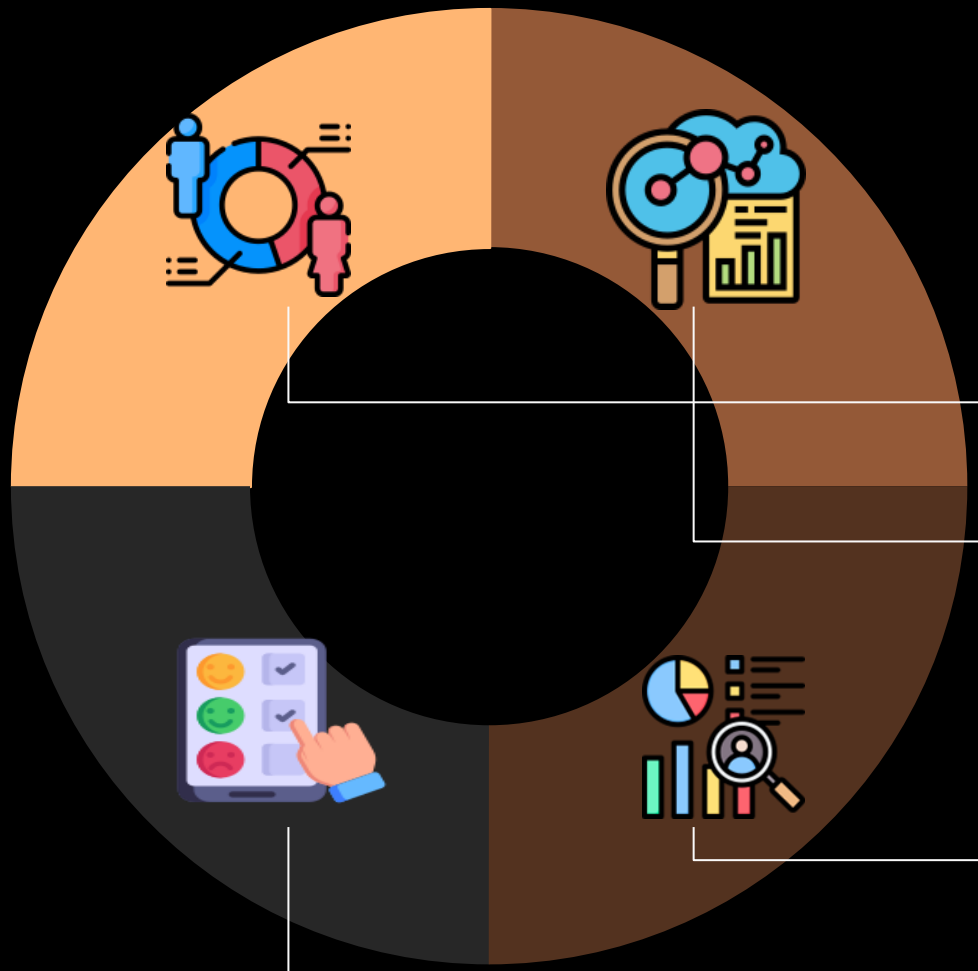
03

New Zealand lacks a national workforce baseline limiting planning, benchmarking, and innovation

Research Design - Overview



Quantitative stage



Workforce demographics

JTF-aligned training needs analysis

Professional development activities currently available

Job satisafction & retention intention

Qualitative Stage

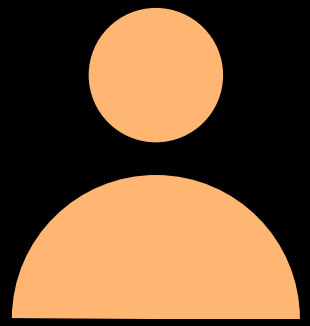
Nuanced understanding of Professional Development (PD) experiences
Contextual influences on competency evolution
Cultural and organisational enablers/barriers

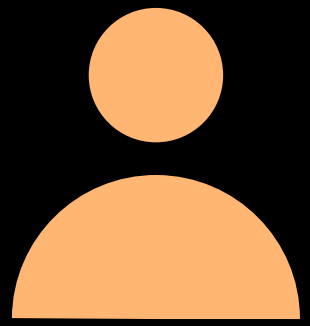
Perceived PD needs

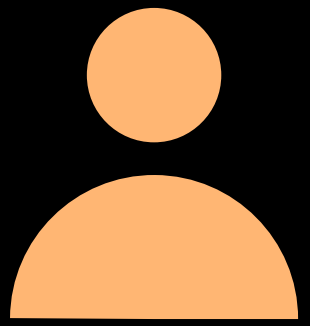
Gaps between current PD provision and what CRCs say they need

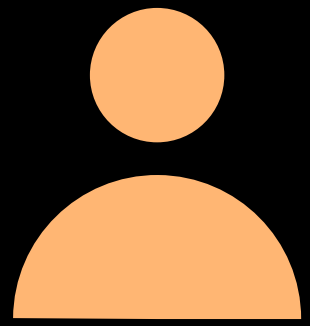
How PD access, or lack of it, affects job satisfaction

Whether and how PD influences intentions to remain in or leave the role









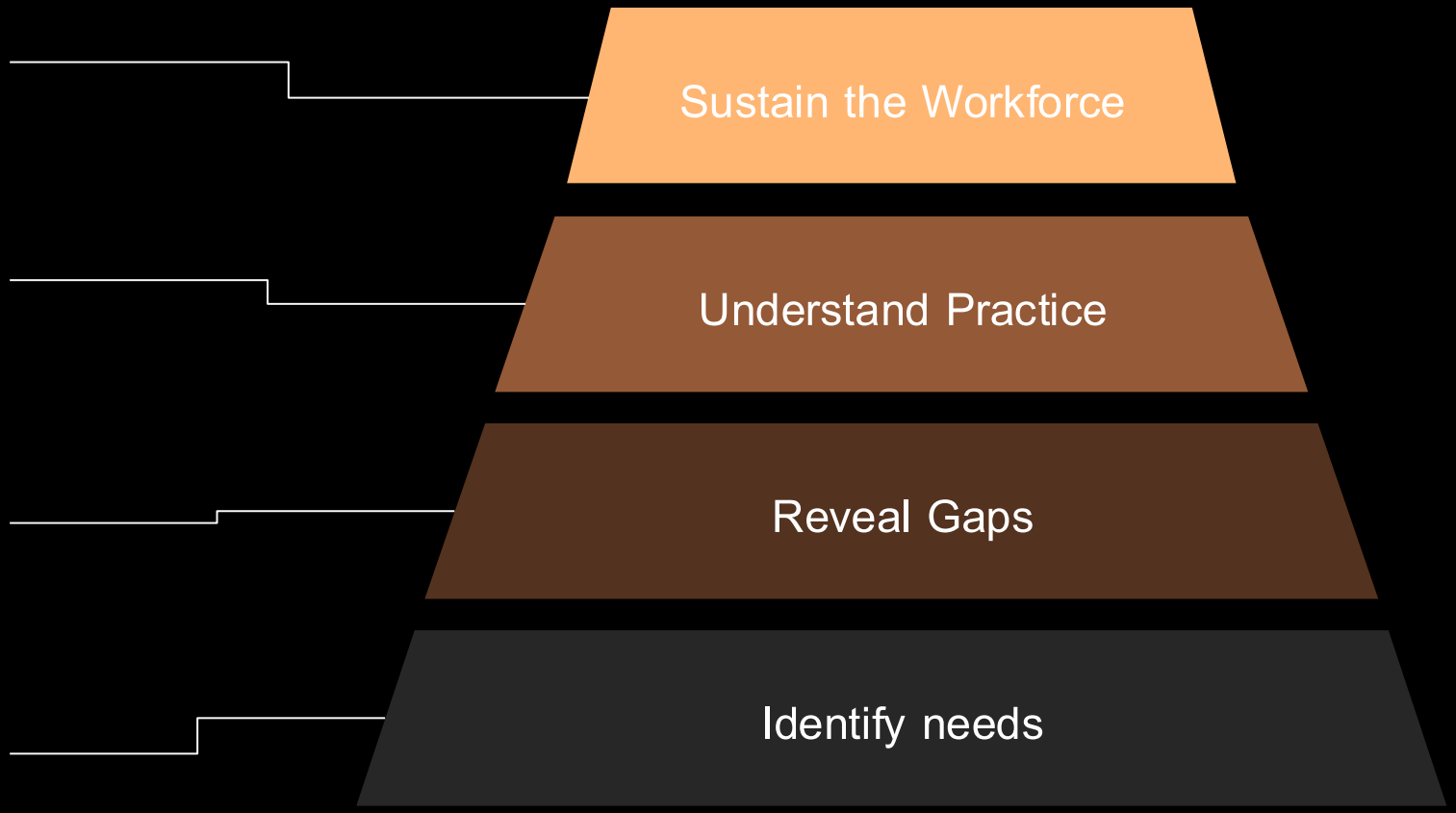
What we expect to learn

Impact on Job Satisfaction and Retention

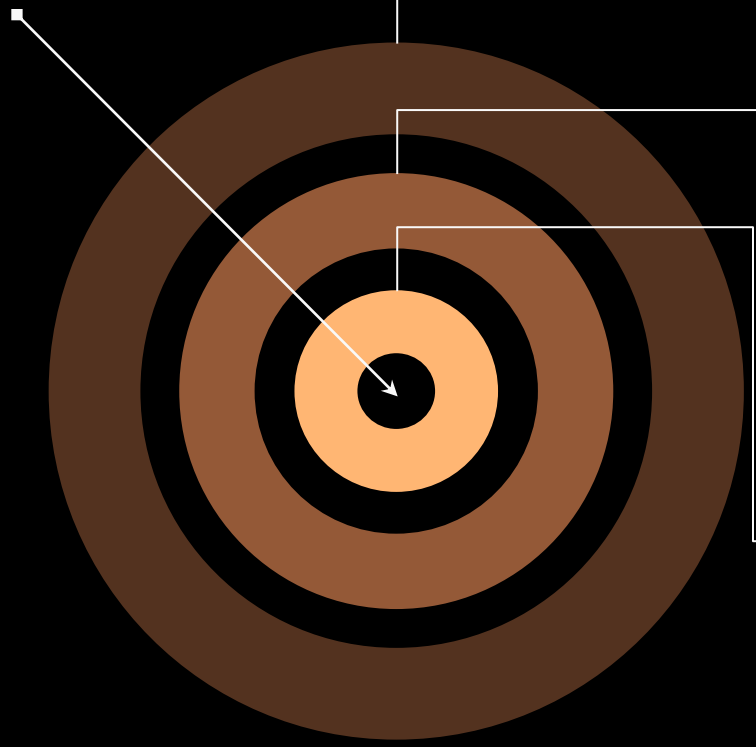
How CRCs Access and Experience PD in Practice

Gaps Between Current PD Provision and CRC Expectations

A National Picture of CRC Professional Development Needs



Towards a National Professional Development Framework

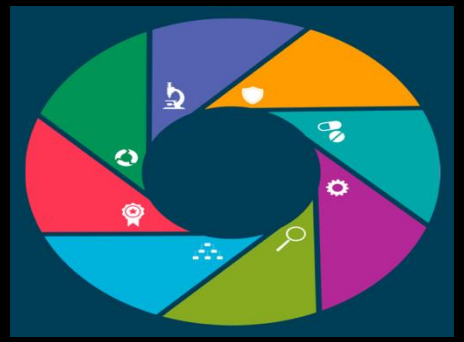


Standardised national onboarding

A JTF-aligned competency assessment tool

A credentialing-light professional recognition pathway

Alignment with Joint Task Force Core Competency Framework



Strengthening the Clinical Research Workforce in New Zealand

JTF Core Competency Framework

- Conceptual base
- Global benchmark

Training Needs Analysis
(**JTF**-Aligned)

- Measures capability
- Identifies gaps

Existing PD
(Health NZ & Praxis Australia)

- Underpinned by **JTF**
- NZ context

National Professional Development Framework

*

"Capability is built one person at a time but transformation happens when we build it together."

https://mrctcenter.org/clinical-trialcompetency/framework/domains/

In Aotearoa New Zealand, we're building a movement that honours culture, grows capability, and ensures everyone has equitable access to world-class research.

Ngā mihi nui – Thank You!

Email: raulle.solcruz@ccdhb.org.nz

Advancing Professional Standards and Recognition for Australian Clinical Trials Professionals

Dr Tim Boyle MChMPP
CEO, ARCS Australia

About ARCS Australia

ARCS Australia Ltd is the national peak body representing life sciences professionals who are advancing innovation in healthcare. For over 40 years, ARCS has supported the sector through professional development, communities of practice, and targeted advocacy. Our members are leaders in shaping the future of medical technology, pharmaceuticals, and healthcare delivery.

Why Professionalism Matters

ARCS AUSTRALIA®

Identifying the Gap – The Fragmented Workforce Landscape

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The ARCS–REDI Grow Program

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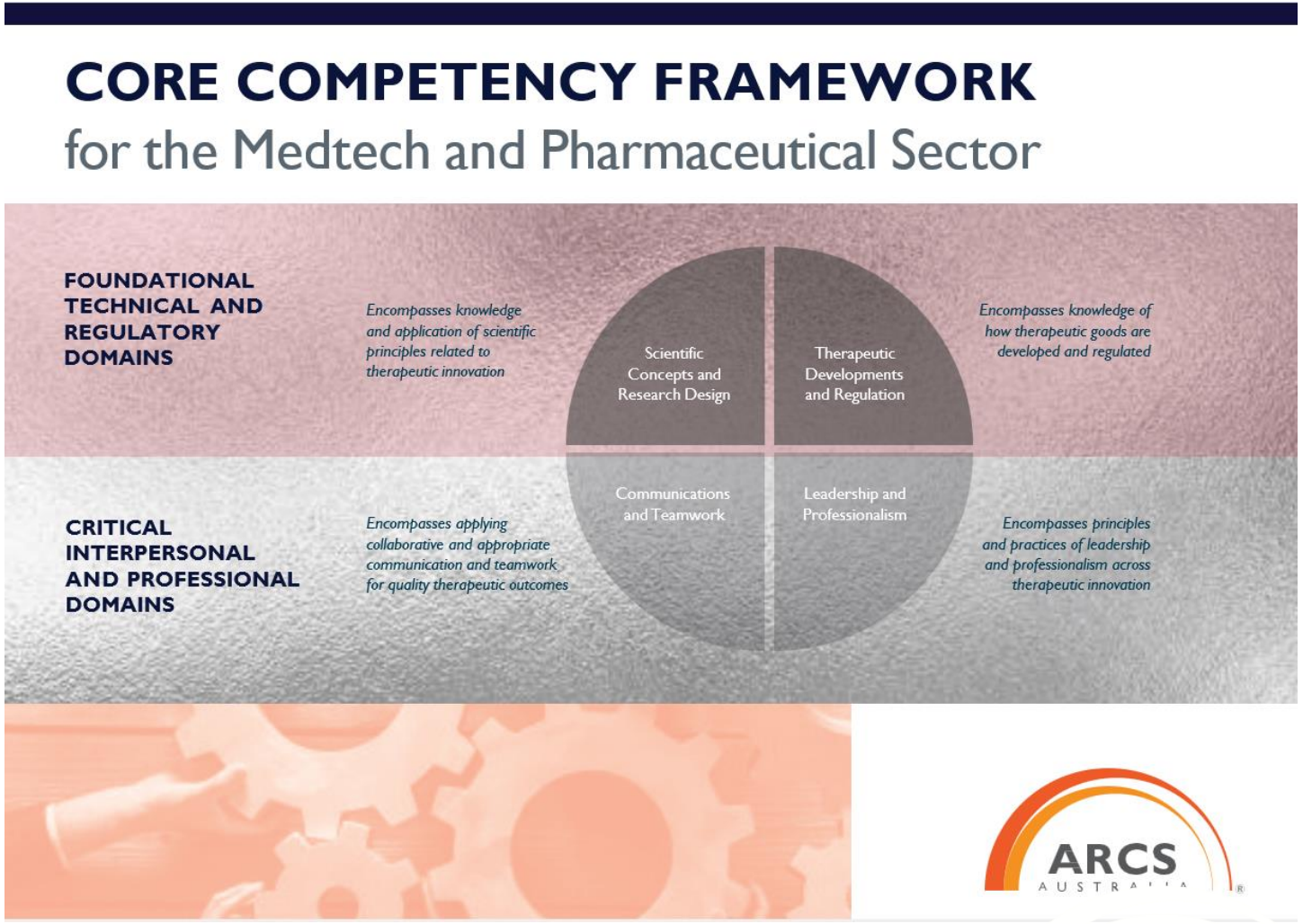
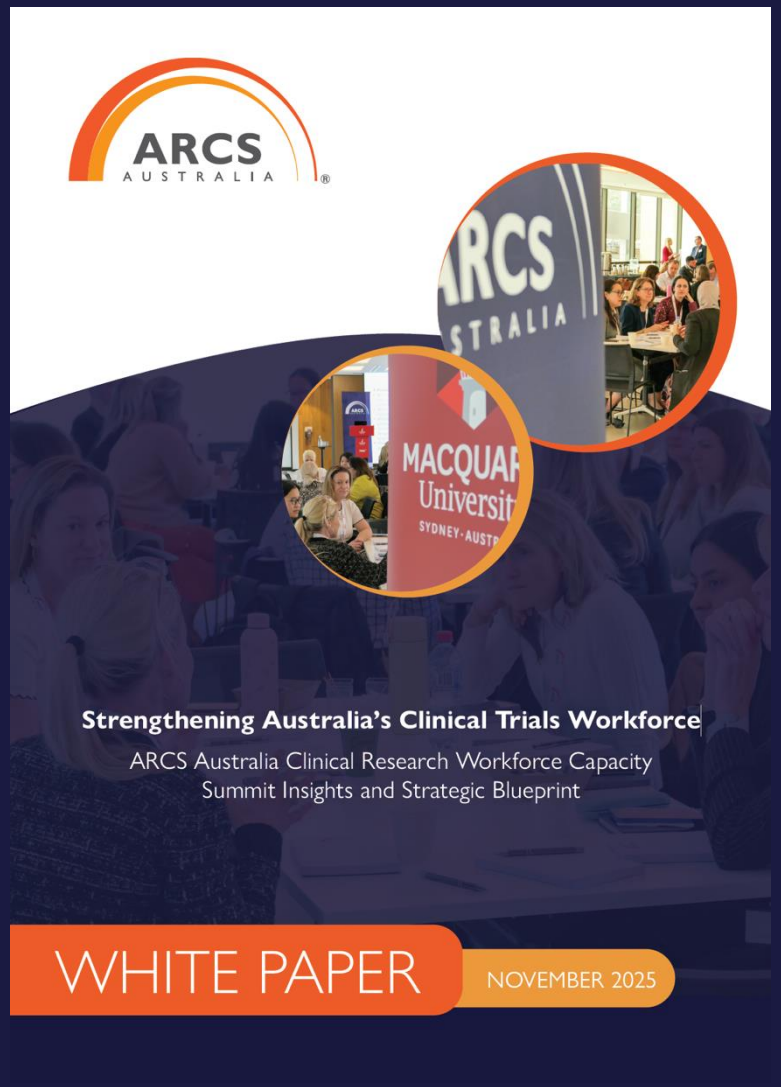
Global Foundations – What We Could Build On

ACRP

From Learning to Leadership



Strengthening Australia's Clinical Trials Workforce



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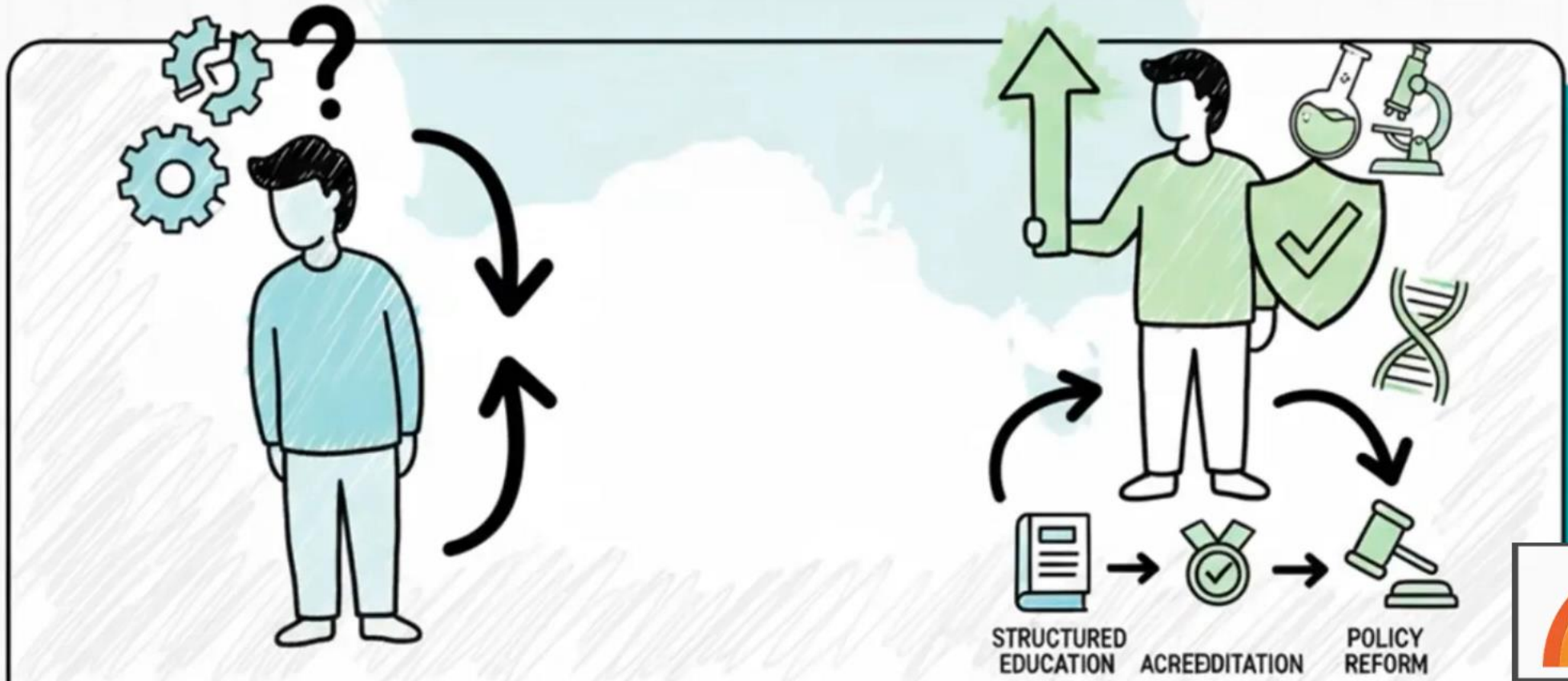
Strengthening Australia's Clinical Trial Workforce



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Toward National Professional Recognition

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Global Alignment and International Collaboration

ARCS AUSTRALIA®

Thank You!

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

Discussion

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

Next JTF Biannual Global Meeting

Monday, 15 June 2026, 9:00-11:00 AM EDT

To register:

https://lp.constantcontactpages.com/ev/reg/t5hg7mt/lp/ad346be2-437e-4fe0-943b-8ecc2d8d1837

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

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