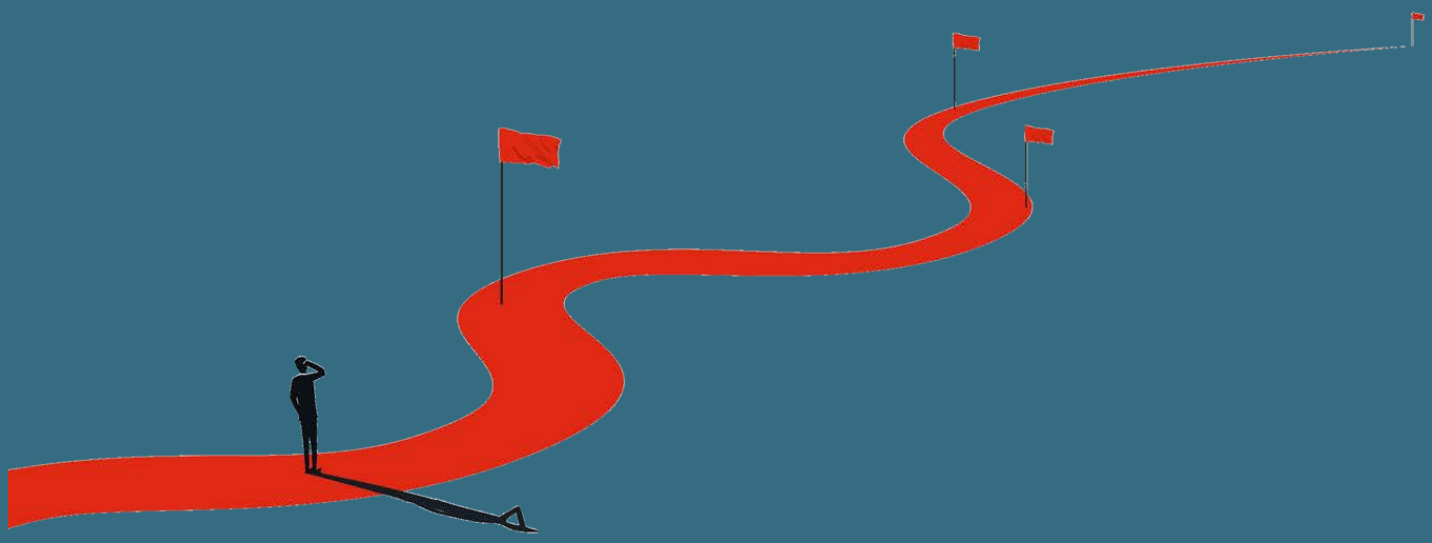
Consortium of
Academic Programs
in Clinical Research

2025 ANNUAL MEETING

Pathways for Clinical Research Careers

POSTER PRESENTATIONS



CONTENTS

Clinical Trials on Adverse Drug Reactions: An In-Depth Analysis Using ClinicalTrials.gov Database

UNCW
University of North Carolina Wilmington
College of Health and Human Services
Clinical Research

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[1]Clinical Research Program, School of Nursing, College of Health and Human Services, UNCW
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Introduction

- Adverse drug reactions (ADRs) remain a major challenge in clinical practice, contributing to patients' health deterioration and increased rate of hospital admissions, and, in severe cases, mortality.
- Clinical trials serve as a primary source for generating high-quality data on drug efficacy and safety, including the identification and characterization of ADRs.
- In clinical trials, improving the detection, prediction, and management of ADRs remains a challenge, but greater awareness of drug safety has advanced trial design and reporting while highlighting research gaps.
- This study presents an in-depth analysis of clinical trials focused on ADRs by leveraging the ClinicalTrials.gov database, one of the most comprehensive registries of clinical studies conducted around the world.
- By examining registered trials, we aim to uncover key trends, gaps, and insights related to the investigation of ADRs. This analysis not only enhances our understanding of the current landscape of ADR-focused trials but also informs future research priorities and regulatory decision-making processes.

OpenAI. (2025). *Adverse drug reactions in clinical trials* [. ChatGPT. https://chat.openai.com/

Study Question & Objective

Study Question. What are the key characteristics, trends, and gaps in clinical trials focusing on ADRs registered in ClinicalTrials.gov from 2020 onward?

Objective. To conduct a comprehensive analysis of clinical trials related to ADRs registered in ClinicalTrials.gov between January 2020 and June 2025, focusing on study design, recruitment status, participant age groups, trial phase distribution, and funding sources.

Methods

Study Design. This study utilized a retrospective cross-sectional design to analyze clinical trials related to ADRs.

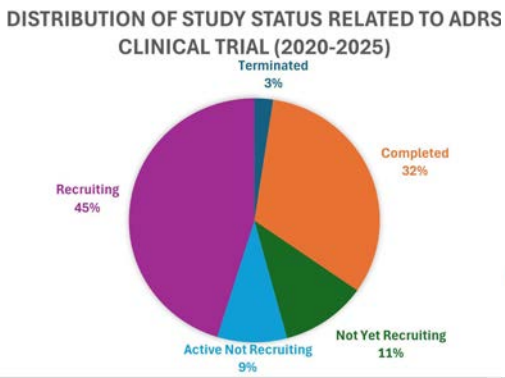
Setting. The data were obtained from ClinicalTrials.gov, a publicly accessible registry of clinical studies conducted globally. The analysis focused on trials registered between January 1, 2020, and June 2025.

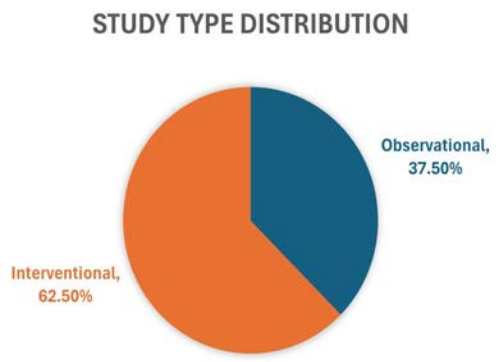
Participants. The "participants" in this context refer to clinical trials (not individual human subjects) registered on ClinicalTrials.gov with relevance to ADRs.

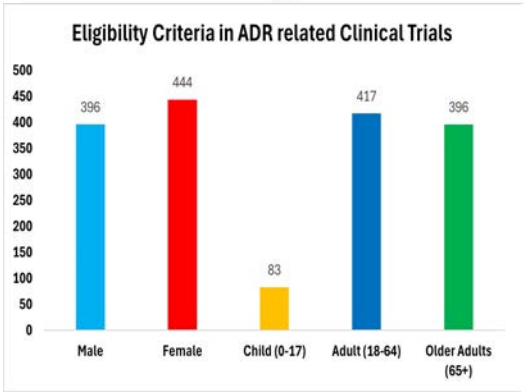
Inclusion/Exclusion. This study included clinical trials registered on ClinicalTrials.gov between January 1, 2020, and June 2025 that contained the keyword "adverse drug reactions." Eligible studies comprised both interventional and observational designs involving human subjects across all phases of drug development. Trials were excluded if their recruitment status was listed as "withdrawn," "terminated," "suspended," "unknown," or "expanded access."

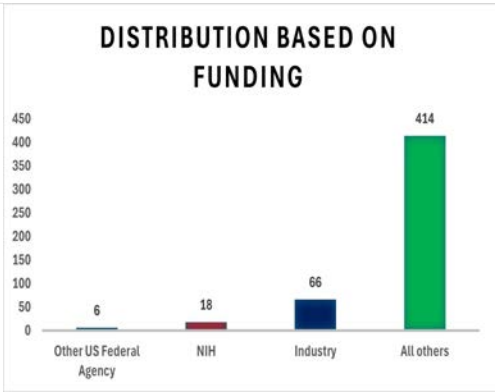
Bias. As a retrospective database analysis, this study is limited by the self-reported nature of the data within ClinicalTrials.gov. Reporting or registration bias may also influence which trials are included in the database. Additionally, the exclusion of incomplete or inactive trials may introduce selection bias.

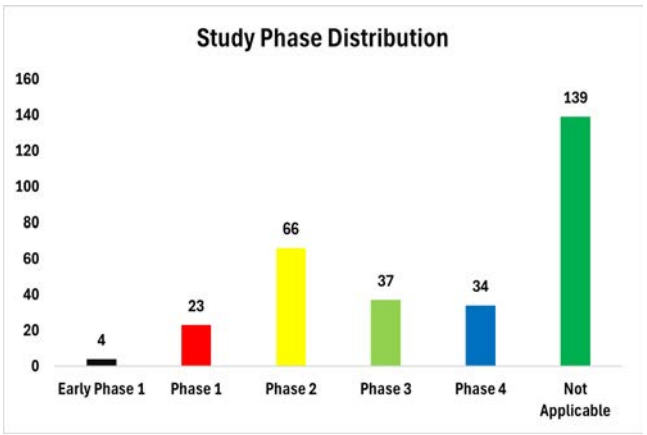
Results







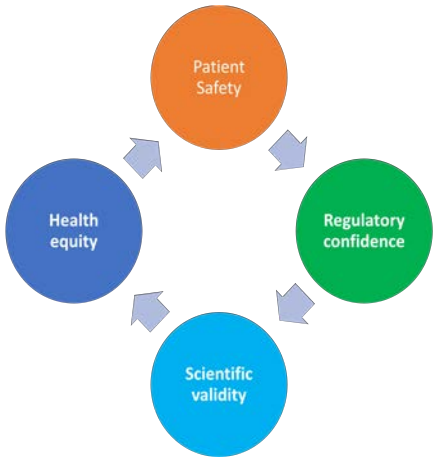




IDENTIFIED GAPS/CONCLUSION

1. Underreporting and Incomplete Trial Data: Many ADR-focused trials are missing crucial details like demographics or full outcome data.
Implication: This limits transparency and hampers secondary analysis across studies.
2. Limited Observational and Real-World Evidence: Clinical trials skew heavily toward interventional designs, with fewer observational studies capturing real-world ADR profiles.
Implication: Trial outcomes may not accurately reflect everyday clinical settings.
3. Narrow Participant Demographics: Pediatric trials are underrepresented.
Implication: Safety profiles specific to children may remain poorly characterized, limiting evidence-based prescribing in this vulnerable group
4. Funding Sources and Phase Distribution: Most studies are funded by "other" fund sources, and are "not applicable" thus safety data may be insufficient or less publicly available.
Implication: Long-term safety risks aren't adequately captured.

Why these Gap matters



About Me

Dr.Mudassar Iqbal
Clinical Assistant Professor/Pharmacovigilance Expert/Affiliate Faculty/Research Fellow

References available upon request.

Onboarding Meaningfully: A Three-factor Competency-based Program for New Clinical Research Professionals

Authors: Jessica R. Cranfill, Christine E. Deeter, Deborah Hannah, Denise C. Snyder, Stephanie A. Freel

Purpose and Objectives

CRP managers need effective, rapid onboarding solutions. Duke's CRP onboarding program accelerates new hire proficiency through a structured, competency-based approach. It includes eLearning, customized learning plans, applied learning activities, and a mentorship program. The standardized tools use a three-factor adult learning approach that is adaptable, shareable, and easily implemented. Duke CRP onboarding program maps 97 courses to clinical research competencies using the JTFCTC framework.

Methods

Introduce
Express Start

Self-paced eLearning modules to introduce responsibilities and the Duke clinical research structure

Learn
Onboarding Learning Plan

Customizable competency-aligned training timelines for every CRP role

Apply
Engagement Activity Packets

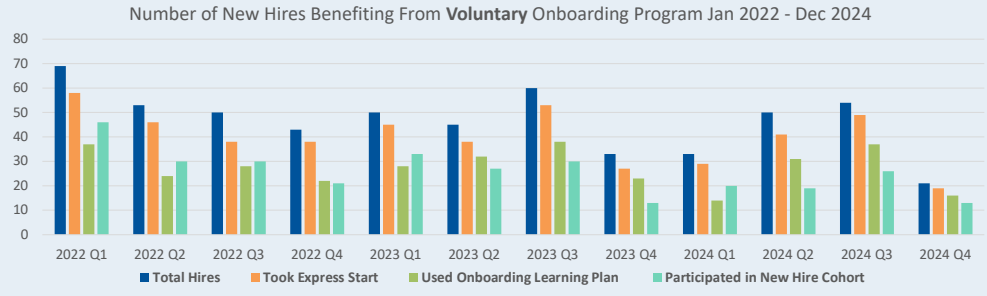
Manager and employee driven applied learning guides with suggested activities

Connect
New Hire Cohorts & Mentoring

Cohort-based mentorship program with four months of group learning and monthly foundational seminars

Results and Impact

Duke's onboarding program enhances CRP development by integrating technical, organizational, and social learning. Designed for broad implementation, it promotes competency-based growth and optimizes onboarding efficiency for managers and employees.

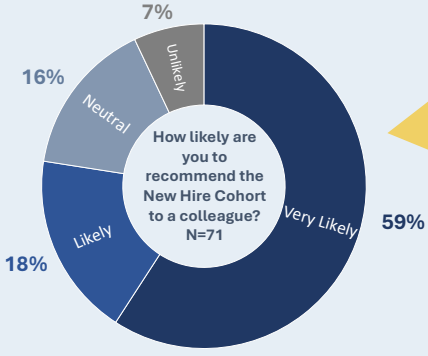


86% Completed **Express Start** for their role

60% Self-identified use of the **Onboarding Learning Plan**

57% Joined a **New Hire Cohort**

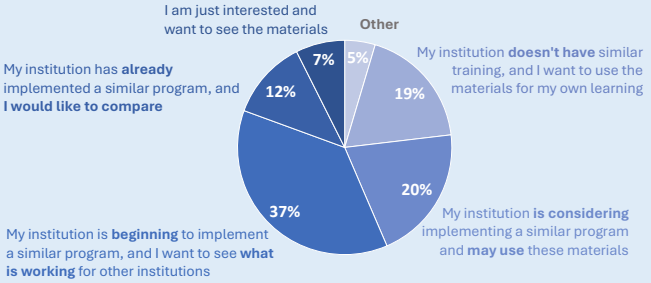
33 CRPs volunteered to mentor a **New Hire Cohort**. Of those volunteers, **23** could use their experience as a mentor to expand their leadership portfolios for career advancement through the Duke CRP tier advancement process.



"The New Hire Cohort has truly been a wonderful and valuable experience that has exceeded my expectations in many ways. The structure, content, and opportunities for growth have been exceptional. It's clear that a lot of thought and effort went into designing a program that would be both engaging and impactful.

My mentor created an environment where everyone felt comfortable sharing their experiences and ideas. I feel that I've gained not only valuable skills and knowledge but also a network of peers that will be beneficial throughout my career. Thank you to everyone involved in making this program such a success. I would highly recommend it to others and look forward to applying what I've learned."

108 individuals from **81** institutions have requested access to the Duke CRP Onboarding Toolkit including an implementation plan and repository of materials.



Duke University School of Medicine

Learn more: Visit https://duke.is/DOCR-WER to learn more and access the Onboarding Toolkit and implementation plan.

The MCR Program at The Ohio State University

100% Online Master of Clinical Research, Graduate CRM Certificate & Undergraduate Clinical Trial Sciences Certificate

Jessica Fritter, DHSc, MCR, ACRP-CP (Director); Marjorie A. Neidecker, PhD, Meng, RN, CCRP; Esther Chipps, PhD, RN, FAAN; Carolynn Thomas Jones, DNP, MSPH, CRN-BC, FAAN

Overview of the MCR Graduate Degree

The 100 % online, asynchronous MCR program prepares students to excel as administrators, regulatory specialists and other professional roles on clinical research teams. Graduates are prepared for rewarding careers as clinical research coordinators and managers, clinical research associates (monitors), project and data managers, clinical research trainers, regulatory compliance officers, institutional review board specialists, research quality analysts and many other positions in the clinical research enterprise.

The program offers a multidisciplinary curriculum, covering the theory and practice of research methods and statistics, the ethics of human subjects' research, the science of pharmacology and medical product regulation, and the business of research operations and management. Coursework is taught by the College of Nursing and Pharmacy. This program is open to applicants with any undergraduate degree (GPA 3.0).
The program concludes with a culminating project where students have an opportunity to apply best practices in clinical research operations or administration.

As a member of the Consortium of Academic Programs in Clinical Research, the MCR graduate degree is designed as a competency-based program. The program's goals and core curriculum aligns with the Joint Task Force for Clinical Trial Competency and CAAPCR/CAAHEP accreditation standards.

Admission Cycles

The MCR program is a 36 credit Masters degree. All programs (degree and certificates) admit students three times per year. Students may select part-time (2 courses per semester) to complete in 24 months, or full-time (4 courses per semester) to complete in 12 months. The Ohio State University is authorized to offer MCR in all 50 U.S. states and territories. As a 100% asynchronous online program students living outside of the U.S. may have in-country acceptance of the degree.

AUTUMN	SPRING	SUMMER
• Opens: Apr 1 • Closes: Jun 30	• Opens: Mar 1 • Closes: July 31	• Opens: Aug 1 • Closes: Mar 31

THE OHIO STATE UNIVERSITY
COLLEGE OF NURSING

MCR Curriculum

The overall MCR program goals are:

Goal 1: Understand the scientific basis of research design and analysis for clinical research and new medical product development. (JTF: 1 & 3)
Goal 2: Assess and apply principles of bioethics and scientific integrity in the protection and care of study subjects in clinical research. (JTF: 2)
Goal 3: Develop skills in applying federal regulations and principles of good clinical practice for the management of studies for clinical research and new medical product development. (JTF: 4, 5, 6)
Goal 4: Demonstrate leadership, cultural and linguistic competence, and effective oral and written communication as a member of the clinical research team. (JTF: 7 & 8)

Core Courses
- Responsible Conduct of Research
- Fundamentals of Medical Product Development and Regulation
- Clinical Research Design and Methods
- Clinical Research Study and Site Management
- Principles of Quality Management for Medical Product Development
- Data Analysis and Interpretation in Clinical and Preclinical Research
- Fundamentals of Pharmacology

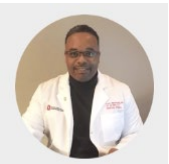
Two Specializations:
1.Clinical Research Management
2.Regulatory Affairs
3.Dual Specialization

Clinical Research Management Specialization Courses
- Project Management for Healthcare and Clinical Research
- Data Management and Informatics in Clinical Research
- Economic Evaluation of Healthcare Interventions
- Pharmaceutical Safety & Risk Management

Regulatory Affairs Specialization Courses
- Regulatory Strategy, Writing and Leadership
- Pharmaceutical Safety & Risk Management
- Federal Regulations of Medical Products
- Principles of Safety Pharmacology

Culmincating Project and ePortfolio (All specializations)
- Culminating Project in Clinical Research

" I learned how to interact with patients from an ethics and safety perspective, as well as how to make sure that research is compliant with domestic and international regulations. You can learn a lot while working in the field, but you won't learn it to the extent that the MCR program will teach you."
- Emily Rice, MCR graduate



"I've made lasting relationships. I still meet my former classmates to discuss processes, improvements and research that we are conducting."
Larry Martin, MCR Graduate

Images: OSU CON

MCR Andragogical Approach for Online Learning

Image: Stock.adobe.com

Redmond & Lock – Online Collaborative Framework, 2006

The MCR Program uses a "backward design" approach in designing and updating online course content. Regular updates are performed based on faculty, student, and stakeholder feedback. A recent audit of the curriculum was completed in 2025 with curriculum updates in the process of approvals. Instructional design and recruitment support is provided by Ohio State Online and the College of Nursing.

As working professionals, 82% of the MCR degree graduate within one to two years of matriculating. Our students have contributed to improvements in the clinical research enterprise.

MCR Graduate Certificate

This online graduate-level Clinical Research Management certificate will provide students with a broad foundation of knowledge and skills in human subjects' research regulations, conduct, management and leadership and meets the internationally recognized Joint Task Force for Clinical Trial Competency framework.

Upon completion of this certificate program, students will be prepared to:
- Systematically apply understanding of regulations, processes and management of human subjects' research, with a focus on clinical trials of drugs and devices.
- Apply bioethical standards to medical development and innovations of complex clinical research studies conducted in the healthcare and biopharmaceutical environment.
- Apply quality improvement, project or data management to support and monitor clinical research studies.

The Clinical Research Management certificate includes 12 credits of graduate coursework (MCR graduate courses), is offered 100% online and asynchronously and is designed to be able to be completed in three semesters. The MCR graduate certificate is available for OSU graduate students and individuals from outside of OSU. At the completion of the program, students earn an academic certificate from The Ohio State University. As a feeder to the MCR degree, credits earned in the CRM Certificate may be transferred to the MCR degree.

MCR Undergraduate Certificate

This certificate is only available to currently enrolled undergraduate students at The Ohio State University.

The **Clinical Trials Sciences Certificate** prepares students who have an interest in human subjects' research regulations, study conduct, management, data coordinating and leadership with a broad foundation of knowledge and skills needed to pursue careers in clinical research.

Upon completion of this certificate, students will be prepared to:
- Systematically apply understanding of regulations, bioethics, design and launch of clinical trials of investigational products.
- Apply data and project management to support quality improvement and monitor clinical trials activities.

This certificate is available to Ohio State students seeking a bachelor's degree in health-related sciences and holding a GPA of 2.0. The Clinical Trials Sciences certificate consists of four courses with a total of 13 undergraduate credit hours, offered completely online:
- o *Medical Terminology for the Health Professions (May substitute Anatomy or Physiology)*
- o *Drug Discovery, Development and Delivery*
- o *Clinical Trials from Concept to Launch*
- o *Clinical Trials Data Management and Monitoring*

At the completion of the program, students earn an academic undergraduate certificate from The Ohio State University making them ready for the entry-level clinical research workforce. Several students either find immediate employment or transition to the MCR program.

Image: nursing.osu.edu

The demand for well-prepared clinical researchers to fulfill roles in academic medical centers, private practice research, contract research organizations and biopharmaceutical companies is growing at an unprecedented rate. Now is the time to break into or expand your career opportunities in the biopharmaceutical and healthcare research industries.

Commission on Accreditation of Allied Health Education Programs

In May, 2023, the MCR Program at The Ohio State University was accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) upon the recommendation of the Committee on Accreditation of Academic Programs in Clinical Research (CAAPCR).

Contact us:
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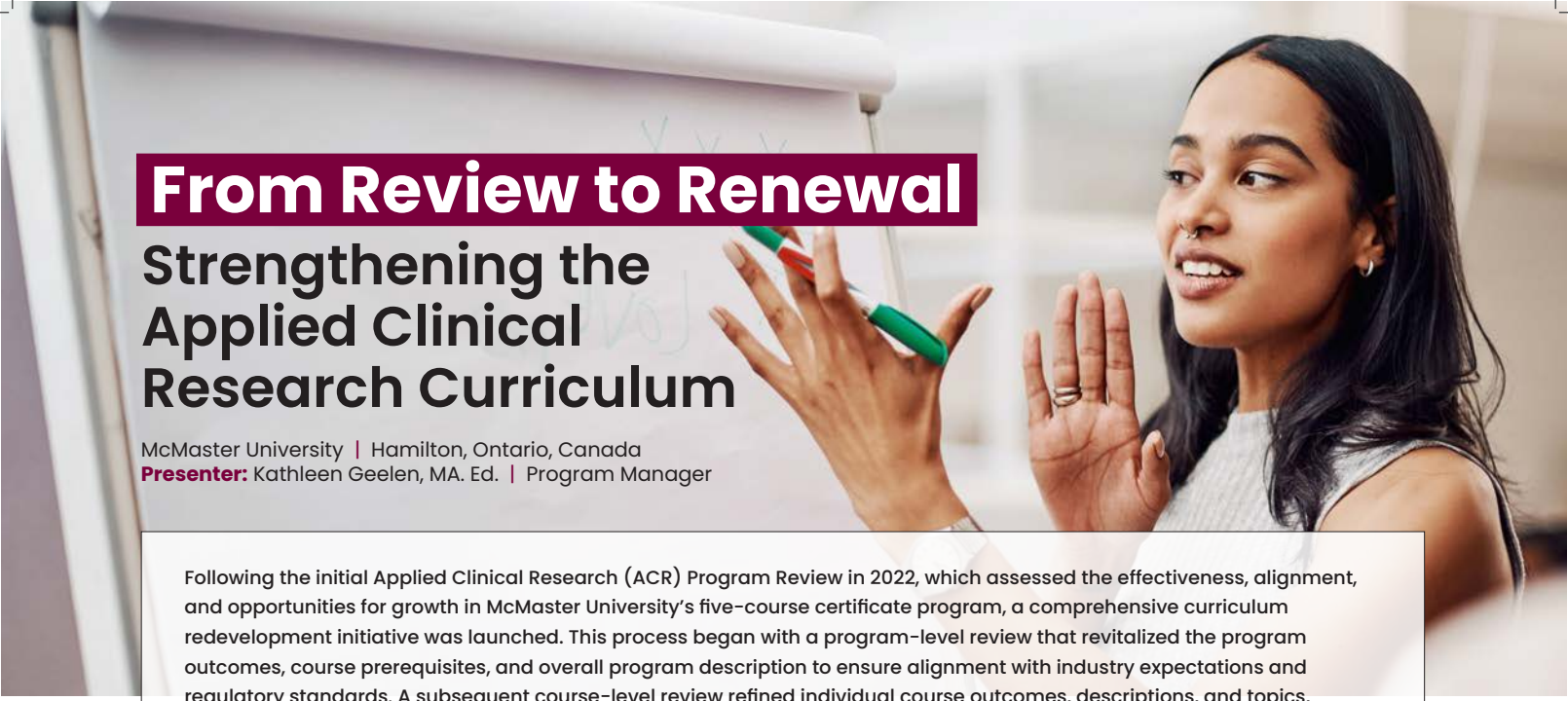


From Review to Renewal

Strengthening the Applied Clinical Research Curriculum

McMaster University | Hamilton, Ontario, Canada
Presenter: Kathleen Geelen, MA. Ed. | Program Manager

Following the initial Applied Clinical Research (ACR) Program Review in 2022, which assessed the effectiveness, alignment, and opportunities for growth in McMaster University's five-course certificate program, a comprehensive curriculum redevelopment initiative was launched. This process began with a program-level review that revitalized the program outcomes, course prerequisites, and overall program description to ensure alignment with industry expectations and regulatory standards. A subsequent course-level review refined individual course outcomes, descriptions, and topics, aligned them with the updated program outcomes, and established targeted assessment strategies to measure learning effectively. Working in a collaborative, facilitated model with subject matter experts and an instructional designer, each course—except the capstone, which was deliberately reserved for last—was revised module by module. This structured redevelopment process has enhanced the program's practical relevance and coherence, ensuring graduates are well-prepared for the evolving clinical research landscape.

Process	People
Program Review	• Program Reviewer • Faculty • Graduates • Industry Representatives
Program Review Report with Recommendations	• Administrative Leadership
Program Curriculum Re-Development • Revise Program Outcomes • Revise Course Outcomes	• InstructionalDesigner • Program Manager • Faculty/Subject Matter Experts
Course Development	• Instructional Designer • Faculty/Subject Matter Experts
Quality Review Program Mapping Course Sign-off Meetings	• Instructional Designer • Program Manager

For more information contact:
Kathleen Geelen
Program Manager, McMaster University
geelenk@mcmaster.ca

McMaster University | Continuing Education

Scan to Watch Presentation

Scan for Program Information

Pathways to Create, Retain, and Sustain Clinical Research Professionals

Shirley LT Helm[1], MS, CCRP; Lauretta Cathers[2], PhD, LMSW; Catherine Brown[1], MEd, CCRP
[1]C. Kenneth and Dianne Wright Center for Clinical and Translational Research; [2]College of Health Professions
Virginia Commonwealth University, Richmond, VA

Supported by: UM1TR004390

Undergraduate Minor in Research Ecosystems

Background: 2025 Institutional Research Workforce: Need Identified

- ✓ VCU Human Resources (HR) identified the Research Jobs Family with the highest turnover and lowest retention rates
- ✓ Recommendations included a formation of a working group to Create and Manage Early Career Pathways; bringing together enterprise wide research representatives
- ✓ The Student Collaborative working group was created, designed, developed, and received approval for Fall 2025 implementation

Research Infrastructure	=	Wright Center: subject matter experts
+		
Academic Expertise	=	College of Health Professions: academic infrastructure & support
+		
Human Resources	=	Institutional Support: Integrated career pathway for graduates.

Curriculum – 18 credits

- Ethical, Legal, Regulatory, and Compliance Issues
- Managing Innovations Across the Research Ecosystem
- Research Study and Site Management Essentials
- Introduction to Team Science and Project Management
- Elective: wide selection
- Internship: 120 hours

Outcomes & Early Impacts

- ✓ Strong student demand for programs
- ✓ Faculty and leadership engagement
- ✓ Growing partnerships for internships and practical training
- ✓ Demonstrated model for workforce development integrated within the university structure

Post-Baccalaureate Certificate in Clinical Research

Background

- ✓ Fall 2020 - program launched
- ✓ Curriculum based upon existing institutional courses – leverages home academic departments
- ✓ Courses aligned with Joint Task Force Clinical Trial Competencies[1]
- ✓ 12 credits beyond Bachelor's (9 required, 3 elective)

Core Audiences

- ✓ Those seeking continuing academic education
- ✓ Those interested in expanding their professional knowledge
- ✓ Those desiring job change / career advancement
- ✓ Those exploring clinical research prior to applying for an advanced degree

Curriculum

Required (9 credits)	JTF Competency Domains	Electives (3 credits)	JTF Competency Domains
Clinical Trials *or* Design Implications in Clinical Trials	1, 6	Team Science Theories and Practice	8
Fundamentals of Research Regulation	2, 3, 4, 5	Professional and Clinical Ethics	2, 5, 7
Scientific Integrity *or* Responsible Scientific Conduct *or* Responsible Conduct of Research	2, 4	Health Care Organization and Leadership	7, 8
		Public Health Ethics	2
Communicating Across Cultures *or* Communication Strategies in Health Services	5, 7, 8	Introduction to Social and Behavioral Sciences	2, 7
		Health Communication	4, 5, 8

Outcomes

- ✓ 17 currently enrolled
- ✓ 13 graduates
- ✓ 46% graduates experienced career advancement
- ✓ 73 % VCU/VCU Health employees
- ✓ 77 % prior CR experience
- ✓ 100 % expressed continuing prof development

[1]Sonstein, S., Seltzer, J., Li, R., Jones, C., Silva, H., & Daemen, E. (2014). Moving from compliance to competency: A harmonized core competency framework for the clinical research professional. *Clin. Res., 28,* 17-23.

Clinical Research Program at UNC Wilmington

Jared G. Kerr & Annemarie Petroff
College of Health and Human Services, University of North Carolina Wilmington, Wilmington, North Carolina

UNCW
University of North Carolina Wilmington
College of Health and Human Services
Clinical Research

Introduction

UNCW's Clinical Research Program offers multiple academic programs to offer students a broad understanding of the science, regulatory, and business aspects of developing new therapies to treat illness and improve quality of life. In 2004, UNCW established the BS in Clinical Research to help address the growing need for clinical research professionals in southeast North Carolina.

Over almost 20 years, UNCW has expanded its academic programs to include a minor, Post-Baccalaureate Certificate in Clinical Research Operations, and MS in Clinical Research and Product Development. The curriculum is a didactic and rigorous curriculum aligned to the harmonized Core Competency Framework from the Joint Task Force for Clinical Trial Competency (Figure 1).

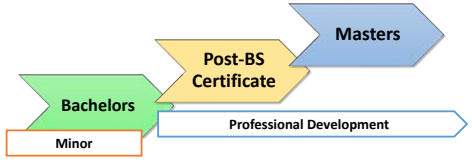
Figure 1. Competency domains for the Clinical Research Professional established by the Joint Task Force for Clinical Trial Competency.

Faculty

- Full-Time Faculty: 8
  - Program Coordinators: 2
  - Tenured/Track: 3
  - Clinical Faculty: 5
- Part-Time Faculty: 6

Courses

Courses are offered in a flexible, online format designed for working professionals. High impact applied learning is an important component of the learning experience and includes internships at medical centers and clinical research organizations across NC and the US.



Learn more

Figure 2. Progression of academic program and professional development.

	MINOR	BS	POST-BACC CERTIFICATE	MS	PROFESSIONAL CERTIFICATES
Founding Year	2015	2004	2017	2010	2017
Enrollment	varies	60	20	30	varies
Program Duration	2 years	4 years	1.5 years	2.5 - 5 years	12 to 24 hrs
Credit Hours	18	120	18	36	non-credit
Audience	STEM and Health Majors	STEM and Health Majors	New or lateral transfers to clinical research	Experienced, midlevel professionals	Workforce/ Professional Development
Instructional Method	Asynchronous, online	Asynchronous, online except internship	Asynchronous, online	Asynchronous, online	Self-paced, online
Internships	No	Yes	Yes	No	N/A
Research Project/Capstone	No	No	No	Yes	N/A
Employment Post-Graduation (3-yr avg)	N/A	85%	90%	100%	N/A

Table 1. Comparison of academic programs and workforce development training.

Undergraduate

Undergraduate

The Bachelor of Science (BS) degree program prepares students with a broad-based understanding of the science, regulatory, and business aspects of developing new therapies to treat illness and improve quality of life.

Program Highlights include:

- Skilled interpretation of Good Clinical Practices and international regulatory guidances
- Business acumen
- Program coordinated internship experience (2 semesters)
- Medidata data management certification
- TransCelerate Certifications
- CliftonStrengths® for self-understanding, personal development and interview preparation

Alumni thrive in a variety of settings including contract research organizations (CROs); clinical settings; biotechnology and medical device companies; and government agencies. Alumni also progress to graduate school.

Graduate

Graduate

- **Graduate Certificate** students are often not experienced in clinical research, but have a background in STEM or health related education and work.
- **MS** students usually work in the clinical research industry. Prepare for mid-to upper-level roles in the biopharmaceutical clinical research industry

Figure 3. Internship site placements in the United States. Sites are indicated by the city name. Number of interns per site is indicated by a density heat map (light green = 1 to orange - >5).
Data based on 2023 placements.

Graduates work in a variety of roles in clinical research while in school or after graduation including clinical operations, pharmacovigilance, study start-up, data management, project management, regulatory affairs, and study coordination. The UNCW Clinical Research Program is committed to developing the clinical research workforce, so they are ready to bring the next medical innovation to improve people's health.

Figure 4. Illustration of companies, vendors, organizations, and community partners who work with UNCW.

Looking Ahead

The Clinical Research Sciences Program at North Carolina Central University

Tracie Locklear, PhD

Biomanufacturing Research Institute and Technology Enterprise & Department of Pharmaceutical Sciences, North Carolina Central University, Durham, North Carolina

ABSTRACT

North Carolina is a global leader in clinical research. This sector contributes more than $1 billion to North Carolina's economy each year and is projected to grow. Clinical researchers and clinical trial scientists work on a variety of projects related to the development and testing of new medications and medical devices for safety and effectiveness. The Clinical Research Sciences Program (CRSP) was established in the Fall of 2018 in partnership with Duke University in a National Institutes of Health Clinical Translational Science Award. Our vision is to build a clinical research workforce of the future with a strong focus on optimal health for all and community engagement. This program is designed with optimization in mind. Our courses are online, hybrid, and face-to-face, to support student learning needs and meet the challenges of a busy life. Students in the Clinical Research Sciences Program can choose from three unique offerings: a Bachelor of Science in Clinical Research, a minor, and a certificate in Clinical Research for students holding a BS degree or pursuing one through our university. We offer our students the knowledge and tools needed to function at a high level in clinical research positions in the local and global industry at every stage of life.

ABOUT US

NCCU ranks 15th nationally as a Historically Black College and University and boasts a top 10 ranking in Social Mobility with a student body of 80% minority students. The university has a well-established workforce development pathway to the pharmaceutical industry through its research institutes, the Biomanufacturing Research Institute and Technology Enterprise (BRITE), and the Julius L. Chambers Biomedical and Biotechnology Research Institute (JLC-BBRI).

The CRS program provides students with three paths to a successful career: a two-semester 12-credit hour certificate in clinical research, an 18-credit hour minor, and a 120-credit hour Bachelor of Science degree in Clinical Research. Separately, these programs target students from varied STEM and health sciences backgrounds who are interested in pursuing careers in clinical research, including roles as biomedical laboratory scientists, community educators, clinical research coordinators, epidemiologists, nurses, pharmacists, and physicians. With formal experience and training in STEM, these are especially well-suited for the clinical research workforce.

CURRICULUM

Certificate in Clinical Research

GET A CERTIFICATE IN CLINICAL RESEARCH IN JUST TWO SEMESTERS 12 total credit hours

FIRST SEMESTER

Course Title	Credits
Principles of Clinical Research	3
Medical Terminology (online)	2
Good Clinical Practice	1
Semester Total	**6**

SECOND SEMESTER

Course Title	Credits
Clinical Trial Management I	3
Clinical Rotation	3
Semester Total	**6**
TOTAL	**12**

Minor in Clinical Research

MINOR IN CLINICAL RESEARCH TO COMPLIMENT YOUR MAJOR 18 total credit hours

Course Title	Credits
Principles of Clinical Research	3
Medical Terminology (online)	2
Good Clinical Practice	1
Clinical Trial Management I	3
Pharmacology	3
Regulatory Sciences	3
Presentation Skills	1
Protocol Design	1
BioBanking & Interpreting Lab Data	1
TOTAL	**18**

B.S. Degree in Clinical Research

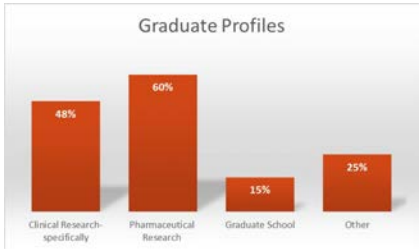
CORE CURRICULUM FOR A B.S. IN CLINICAL RESEARCH

120 total credit hours including core classes listed below

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 Rotation	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
Protocol Design	1
BioBanking & Interpreting Lab Data	1
Good Clinical Practice	1
Clinical Research Internship	14
TOTAL	**59**

(to be added to General Ed courses for a total of 120)

WHY US?



- Bachelor of Science degree program conveniently located in the Triangle area
- NC Biotech, Duke CTSI, and NIH CTSA collaborations
- Member of Consortium of Academic Programs in Clinical Research
- Experiential Learning/Internship Opportunities
- Integrated learning (e.g., translational research exposure)

QUOTES FROM GRADUATES

- "[The CRS program] helped my career tremendously and honestly I feel more than my 4 [year] degree did"
- "[The CRS program] given me opportunities and responsibilities I know I wouldn't have been offered without the knowledge and skills I obtained through the program"
- "Every person I've interviewed with has said this was a great addition to my resume."
- "I believe that the program has been an enhancement to my career. I see many of my peers that are currently pursuing the CRS certification at NCCU and I am glad I pursued it when I did."

CONTACT INFORMATION

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Website: https://www.nccu.edu/chas/pharmaceutical-sciences/clinical-research-science-program/program-leaders-message

Discover what's Central to you.

UAB The University of Alabama at Birmingham

Biotechnology Regulatory Affairs Certificate Program
Cross-Disciplinary Innovation in Regulatory Affairs Education
School of Health Professions, Clinical and Diagnostic Sciences
Kimberly McCall, PhD, Assistant Professor/Regulatory Affairs Specialist; Tino Unlap, PhD, Professor/Program Director; Joseph Garner, PhD, Assistant Professor; Kathy Nugent, PhD, Associate Professor; & Dina Avery, DHSc, Assistant Professor

Introduction

The **Biotechnology Regulatory Affairs Graduate Certificate Program** at UAB provides specialized training for professionals navigating the complex regulatory landscape of biotechnology, pharmaceuticals, and medical devices. As regulatory knowledge becomes increasingly essential across healthcare and research sectors, this program equips learners with the foundational tools to understand and apply U.S. federal regulations in real-world contexts.

Designed for professionals such as **scientists, clinicians, biomedical engineers, entrepreneurs, and quality assurance experts**, the certificate also supports companies seeking to bring innovative products to market.

Curriculum

100% Online. Learn it here. Use it everywhere

Requirements
- BS degree with min. 3.0 GPA
- Meet UAB Graduate School requirements
- TOEFL, IELTS AND TWE scores (international students)

Curriculum (Earn your certificate in only 5 Courses)
- **BTR 605**: Biotechnology Regulatory & Quality Systems
- **BTR 615**: Applications of Biological Processes in Drug Development
- **BTR 620**: Food and Drug Law
- **BTR 640**: Clinical Development of Drugs, Biologics, Diagnostics, and Medical Devices
- **BTR 690**: Clinical Trial Implementation

Optional Practical Training (OPT)-Up to 2 years – International Students
- Complete during Training
- Applies labs, human studies, animal, or behavioral studies

Additional Benefits
- Stackable credential for career mobility
- Pathway to regulatory affairs roles in biotech, pharma, and clinical research
- **Master's Pathway: Combine the certificate with UAB's Interdisciplinary Graduate Studies (IGS) program to create a customized Master's degree 100% online** and designed for flexibility and career advancement

Undergraduate Enrollment

Open to Select Undergraduates

- The Biotechnology Regulatory Affairs Certificate offers open enrollment to undergraduates on a **case-by-case basis**, allowing students to potentially complete a graduate certificate at the same time they earn their undergraduate degree.

Undergraduate Enrollment Requirements

- Approved on a case-by-case basis.
- Must have at least **60 credit hours completed**.
- At least **36 credit hours must be taken at UAB.**
- The certificate **will not be awarded until students complete their undergraduate degree**.

PhD Curriculum Integration

The Biotechnology Regulatory Affairs Certificate Program is fully cross-listed at the 700-level for students in the **PhD in Biotechnology** program, ensuring advanced academic rigor and relevance to doctoral-level research and leadership development.

Curriculum Integration:
All five BTR courses are available to PhD students. Some are required, while others may be taken as electives, allowing students to customize their training in regulatory science.

Certificate Option for PhD Students:
Students who complete all five courses may formally apply to earn the Graduate Certificate in Biotechnology Regulatory Affairs in addition to their PhD.

Faculty Mentorship & Engagement:
BTR faculty actively serve on dissertation committees, mentor doctoral candidates, and advise students pursuing regulatory-focused research, providing interdisciplinary support and academic leadership.

Strategic Impact:
This integration strengthens UAB's commitment to preparing future leaders in biotechnology, clinical research, and regulatory affairs bridging academic excellence with workforce readiness.

JTF Curriculum Alignment

The Biotechnology Regulatory Affairs Certificate Program at UAB is designed to reflect key domains from the **Joint Task Force for Clinical Trial Competency (JTF) framework**. The curriculum currently aligns with four core domains, ensuring students gain foundational knowledge and skills relevant to clinical research and regulatory affairs.

Current Domains Covered:

Domain 1: Scientific Concepts & Research Design
Domain 2: Ethical & Participant Safety Considerations
Domain 3: Investigational Product Development & Regulation
Domain 4: Clinical Study Operations (Good Clinical Practice)

Ongoing Development:
The program is actively working toward incorporating all eight JTF domains in future course revisions, expanding the scope and depth of regulatory science training.

Collaborative Pathways: Nursing Clinical Management

The **School of Nursing** and **SHP-CDS** have established a strategic partnership to guide students toward specialized training in **clinical management** and **regulatory affairs**. **Referral Collaboration**: Students in Nursing Clinical Management are referred to the **Biotechnology Regulatory Affairs (BTR) Certificate Program** for regulatory-focused coursework.

- **Elective Integration**: **BTR courses may be used as electives within the Nursing Clinical Management curriculum or combined toward an Interdisciplinary Graduate Studies (IGS) master's degree**.
- **Shared Educational Goals**: Both programs emphasize leadership, compliance, and innovation in clinical research and healthcare regulation.
- **Future Program Development**: A joint master's degree in Clinical Management and Regulatory Affairs is under proposal, combining the strengths of both academic units.

This collaboration supports interdisciplinary learning and career advancement in the evolving landscape of clinical trials and regulatory science.

Email: Kmccall@uab.edu
Website: uab.edu/shp/cds/biotechnology-regulatory-affairs-certificate
uab.edu

PennState Clinical and Translational Science Institute | PennState Greater Allegheny | PennState College of Medicine

Pennsylvania State University's Undergraduate Clinical Research Training Program

Andrea Jacobs Stevens, MS, PhD

auj139@psu.edu

Program Director, Penn State Undergraduate Clinical Research Training (UCRT) Program, Pennsylvania State University
Assistant Professor, Microbiology, Pennsylvania State Greater Allegheny
Clinical and Translational Sciences Association, Pennsylvania State University

Program Mission

A **career exploration** program that provides a **pipeline pathway** into the clinical research profession for **undergraduate students** in the sciences who may not have sought the field otherwise. We strive to train the **next generation** of clinical researchers by preparing them with a foundation in the clinical research core curriculum and hands-on internship opportunities, whilst networking with peers and fellow professionals in clinical research.

Aim: *increase the workforce by directly training students pursuing their Bachelor's degree*

Outcome: *increases diversity in the workforce* population

Program Goals

This program was originally developed to **increase the workforce** in clinical research by obtaining trainees during their undergraduate education.

It is a unique approach in that most individuals entering the field have either prior experience or post-baccalaureate training and/or education.

By **targeting students** during their undergraduate training who have an interest in biomedical research or healthcare, it serves as a mechanism to help direct their future work.

Undergraduate-Focused Clinical Research Training Program

This is a **shared campus** program with:
- Greater Allegheny (McKeesport, PA)
- New Kensington
- Harrisburg
- University Park (State College, PA).

Rural and urban outreach

Figure 1. Image of map of Penn State Campuses. Image courtesy of Penn State Greater Allegheny.

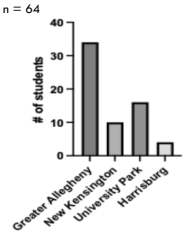
HHD 410/ BBH 471 → Internship → Career development opportunities → Hands-on training → Post-baccalaureate career plans

Program Criteria:
- Entry via application
- 3rd year status
- Biobehavioral Health, Kinesiology, and other life-science majors
- Must demonstrate a proficiency in life science coursework
- Interest in biomedical research
- Prior undergraduate research experience

Student Demographics

Greater Allegheny Campus (McKeesport, PA)
- Situated outside of Pittsburgh
- 'First generation' campus
- >50% PHEA-eligible
- 2- and 4-year programs
- Undergraduate research labs

Figure 2. Campus distribution of program participants.
n = 64



Inaugural group of interns at CoM in 2023.

Figure 3. Ethnic background of program participants. n = 64.

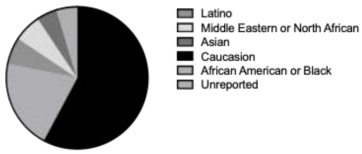
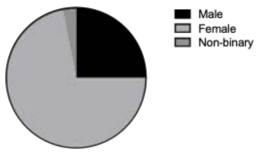


Figure 4. Gender of program participants.
n = 64



Practice-Oriented Education

Capstone Course: Clinical Research Practice (HHD410)

ACRP Core Competency Guidelines for Clinical Research Coordinators (CRCs)™

NACE®

First half: Theoretical concepts and bioethics
Second half: Practical application of site management with **guest lecturers** (study team members)
Career Readiness (Resume & portfolio development, LinkedIn, Interview & Networking skills, CITI Training, Teamwork, Communications, Equity and Inclusion)

Curated, Paid Internships designed for our students

Program Structure

Career Trajectories

Figure 5. Internship Opportunities.

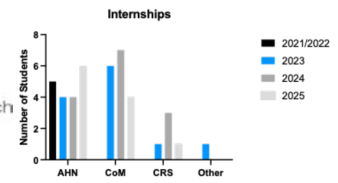
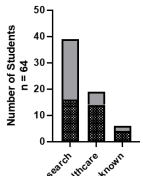
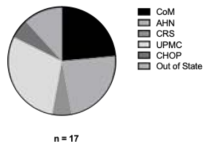


Figure 6. Career trajectories of program participants.



61% of UCRTP students have, or plan, a career in Clinical Research



n = 17

Future Directions

Develop Minor or Certificate → ACRP Accreditation → Increase likelihood to enter CR

Seek **accreditation** as an undergraduate **minor or certificate**

Continue recruiting **high-quality** applicants

Increase the number of internships and **sites**

Adjust to Commonwealth Campus realignment

Acknowledgements

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Clinical Research Administration & Regulatory Affairs Programs at The George Washington University

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THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

School of Medicine & Health Sciences
THE GEORGE WASHINGTON UNIVERSITY

OVERVIEW OF THE PROGRAMS

- **100% online & asynchronous**
- **High quality, cutting-edge curriculum based on the Joint Task Force for Clinical Trial Competency Framework.**
- **Outstanding faculty with clinical research and regulatory affairs experience at FDA, NIH, major pharmaceutical and biotech companies, major CROs and prominent academic medical centers.**
- **Member of the Consortium of Academic Programs in Clinical Research (CoAPCR)**

GRADUATE CERTIFICATE IN REGULATORY AFFAIRS

- **12 credit hours; 12-16 months part time; 100% online**

LEARNING OBJECTIVES:

- **REGULATIONS**
- Analyze domestic and international law, regulations, and guidance documents covering pre- and post-market requirements for medical products.
- **QUALITY AND COMPLIANCE**
- Evaluate quality systems and standards and their impact on product and public safety in the context of regulatory Affairs
- **STRATEGY**
- Appraise strategic approaches to product development, market approvals, and marketing

COURSE WORK:

- **RCR 6201** Introduction to Global Regulatory Affairs and Clinical Research
- **RCR 6202** Regulatory Strategy in the Development of Therapeutics
- **CRA 6204** The CR Industry
- **One elective from the following list:**
  - **CRA 6203** Human Subjects
  - **CRA 6211** Monitoring, Auditing & Oversight in CR
  - **RCR 6206** International Regulatory Affairs and Clinical Research

GRADUATE CERTIFICATE IN CLINICAL RESEARCH ADMINISTRATION

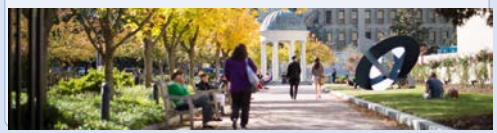
- **12 credit hours; 12-16 months part time; 100% online**

LEARNING OBJECTIVES:

- **REGULATIONS AND FUNDAMENTALS OF CLINICAL DEVELOPMENT**
- Explain and assemble the components of clinical and regulatory plans for the development of investigational therapeutics that adhere to domestic and international laws, regulations, and pre- and post-approval requirements.
- **LEADERSHIP AND STRATEGY**
- Appraise and apply strategies to lead interdisciplinary teams to ensure successful pharmaceutical/medical device product development, regulatory approvals, and marketing activities.
- **QUALITY AND COMPLIANCE**
- Describe and select strategies to ensure clinical trial diversity, ethical conduct, patient safety, data integrity, and compliance with domestic and international laws and regulations when developing new therapeutics.
- **BUSINESS ACUMEN**
- Identify and evaluate elements of the therapeutic product lifecycle to address the evolving global legal, clinical, and regulatory requirements in the healthcare industry.

COURSE WORK:

- **RCR 6201** Introduction to Global Regulatory Affairs and Clinical Research
- **RCR 6202** Regulatory Strategy in the Development of Therapeutics
- **CRA 6204** The CR Industry
- **One elective from the following list:**
  - **CRA 6203** Human Subjects
  - **CRA 6211** Monitoring, Auditing & Oversight in CR
  - **RCR 6206** International Regulatory Affairs and Clinical Research



MSHS IN REGULATORY AFFAIRS & CLINICAL RESEARCH LEADERSHIP

- **36 credit hours; 24 months part time; 100% online**
- **Two Concentrations Available:**
  - **Clinical Research Administration**
  - **Regulatory Affairs**

LEARNING OBJECTIVES:

- **REGULATIONS AND FUNDAMENTALS OF CLINICAL DEVELOPMENT**
- Create clinical and regulatory plans for the development of investigational therapeutics that adhere to domestic and international laws, regulations, and pre- and post-approval requirements.
- **LEADERSHIP AND STRATEGY**
- Lead interdisciplinary team to develop strategies to ensure successful pharmaceutical/medical device product development, regulatory approvals, and marketing activities.
- **QUALITY AND COMPLIANCE**
- Formulate strategies to ensure clinical trial diversity, ethical conduct, patient safety, data integrity, and compliance with domestic and international laws and regulations when developing new therapeutics.
- **BUSINESS ACUMEN**
- Strategize the therapeutic product lifecycle to address the evolving global legal, clinical, and regulatory requirements in the healthcare industry.

COURSE WORK:

- **CORE COURSES (7 courses);**
- **RCR** 6201 Introduction to Global Regulatory Affairs and Clinical Research
- **RCR** 6202 Regulatory Strategy in the Development of Therapeutics
- **RCR** 6206 International Regulatory Affairs and Clinical Research
- **HSCI Epidemiology**
- **COHM 6235** Leadership Development in Healthcare Systems
- **COHM 6245** Strategic and Operational decision making for Healthcare leaders
- **RAFF/ CRA 6275** Leadership in Regulatory Affairs/Clinical Research (Capstone Course)

MSHS IN REGULATORY AFFAIRS & CLINICAL RESEARCH LEADERSHIP (Continued)

CRA CONCENTRATION COURSES (5 courses):

- **CRA 6203** Partnerships with Human Subjects
- **CRA 6204** The Clinical Research Industry
- **CRA 6209** Quality and Risk Management
- **CRA 6211** Monitoring, Auditing, and Oversight in Clinical Research
- **One Elective Course:**
  - **HCQ 6201** Building a Quality Culture,
  - **HSCI 6263** Biostatistics Translational Research
  - **RAFF 6204** Clinical Research for Regulatory Affairs
  - **RAFF 6205** Regulatory Compliance
  - **RAFF 6207** Promotion of FDA-Regulated Medical Products

REGULATORY AFFAIRS CONCENTRATION COURSES (5 courses):

- **RAFF 6203** Regulatory Strategy in the Development of Devices and Diagnostics
- **RAFF 6204** Clinical Research for Regulatory Affairs
- **RAFF 6205** Regulatory Compliance
- **RAFF 6207** Promotion of FDA-Regulated Medical Products
- **One Elective Course:**
  - **HCQ 6201** Building a Quality Culture,
  - **HSCI 6263** Biostatistics Translational Research
  - **RAFF 6204** Clinical Research for Regulatory Affairs
  - **RAFF 6205** Regulatory Compliance
  - **RAFF 6207** Promotion of FDA-Regulated Medical Products

Health Equity Knowledge, Capacity and Attitudes of Clinical Research Administration Students: Curriculum Implications - 2025 Update

Kathleen A. Thoma, EdD, CCRP, CPH[1], MPH; Rohini Ganjoo, PhD[2] & Maranda C. Ward, EdD[1]
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School of Medicine & Health Sciences
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WHAT IS HEALTH EQUITY?

- Health equity is ensuring that all individuals have a fair and just opportunity to attain the highest level of health (CDC, 2025).
- It involves lowering economic and social barriers, addressing historical and contemporary injustices, eliminating health and healthcare disparities, and ensuring that everyone has equitable health-related resource allocation.

WHY IS HEALTH EQUITY IMPORTANT FOR THE FIELD OF CLINICAL RESEARCH?

- It is important that all individuals have equitable access to clinical trials and are equitably represented because lack of representation negatively impacts the generalizability of clinical trial results, leading to dangerous gaps in therapeutic availability (Habibzadeh, 2022).

WHY IS AN UNDERSTANDING OF HEALTH EQUITY IMPORTANT FOR CRA STUDENTS?

- It is important for the future clinical trials workforce to be educated about health equity and have the capacity to translate it into practice because they are "stewards of health equity".
- As "stewards of health equity", the clinical trials workforce has the responsibility and obligation to ensure that access to clinical trials is equitable and all population groups are represented.

PURPOSE AND METHODS

- In 2021, GWU SMHS faculty/researchers developed a 36 item validated survey based on Peterson et al.'s (2020) Health Equity Framework in order to measure health equity knowledge, capacity and attitudes among new health professions students.
- Between 2022 and 2024, 314 new GW SMHS and nursing students from 8 programs completed the survey of which 16 were in the Clinical Research Administration Programs.

RESULTS

Note: *these are preliminary results from a small sample size. The purpose is to indicate trends that can inform curriculum planning.*

Race	#
Asian	1
Black/African Descent	4
Hispanic/Latino	2
White/European	8
No response	1

Age	#
20-25	2
26-30	2
31-35	1
36+	11

Gender	#
Male	2
Female	14

Respondents were given a series of statements related to health equity.

The following statements had a high percentage of correct responses:

Access to healthcare is more than having insurance.

Health disparities affect groups of all ages.

Health literacy in the U.S. is only an issue for English language learners.

Percentage who correctly answered "TRUE"

2022	2023	2024	Total
100%	100%	100%	100%

The following statements had moderate correct response rates:

Improving the health of the least socially advantaged groups improves the health of all groups.

Percentage who correctly answered "TRUE"

2022	2023	2024	Total
87.5%	100%	83.3%	87.5%

RESULTS

The following statements had lower rates of correct responses. Those with 75% or fewer correct answers are flagged in red.

The health disparities that LGBTQIA+ populations face is underreported partly due to the lack of standardized sexual orientation and gender identity data.

Percentage who correctly answered "TRUE"

2022	2023	2024	Total
75%	100%	83.3%	81.25%

Chronic stress and poor diet can change the expression of genes.

Percentage who correctly answered "TRUE"

2022	2023	2024	Total
87.5%	50%	100%	87.5%

Eating healthy is an issue of personal responsibility, not an issue of access.

Percentage who correctly answered "FALSE"

2022	2023	2024	Total
87.5%	100%	66.67%	81.25%

Social policy is health policy.

Percentage who correctly answered "TRUE"

2022	2023	2024	Total
75%	50%	83.33%	75%

Where people live determines how long they live

Percentage who correctly answered "TRUE"

2022	2023	2024	Total
75%	50%	66.67%	68.75%

Health professional shortages contribute to the high rates of U.S. maternal morality.

Percentage who correctly answered "TRUE"

2022	2023	2024	Total
62.5%	50%	66.67%	62.5%

RESULTS

If the U.S. spends more money on healthcare, it will automatically improve life expectancy.

Percentage who correctly answered "FALSE"

2022	2023	2024	Total
50%	50%	33.33%	43.75%

Health equity focuses on improving the health of minority populations.

Percentage who correctly answered "FALSE"

2022	2023	2024	Total
37.5%	0%	33.33%	31.25%

Eliminating individual risk behaviors (i.e. smoking, poor eating habits, etc.) will reduce health disparities.

Percentage who correctly answered "FALSE"

2022	2023	2024	Total
0%	50%	33.33%	18.75%

DISCUSSION

- These results will help GW CR and RA program directors design curriculum and learning activities to strengthen students' health equity knowledge and application in clinical research.
- The survey will continue to be administered to new student cohorts and again at program completion to measure changes in health equity knowledge, capacity, and attitude.
- The researchers plan to share the survey with other institutions and use accumulated data to inform standardized health equity competencies for health science students.

REFFERENCES

Centers for Disease Control and Prevention (CDC). (2025). *About health equity.* https://www.cdc.gov/health-disparities-hiv-std-tb-hepatitis/about/index.html

Habibzadeh, F. (2022). Disparity in the selection of patients in clinical trials. *The Lancet, 399*(10329), 1048. https://doi.org/10.1016/S0140-6736(22)00176-3

Peterson, A., Charles, V., Yeung, D., Coyle, K. (2021). The health equity framework: A science and justice-based model for public health researchers and practitioners. *Health Promotion Practice, 22(6)*, 741-746. https://doi.org/10.1177/1524839920950730