

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)

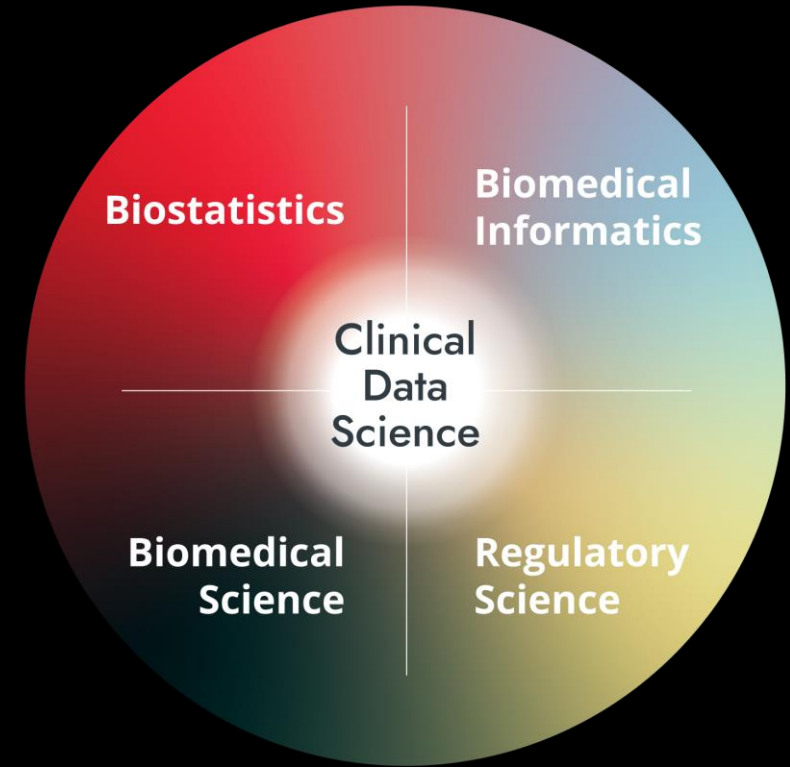


Purpose

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



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 = $f(\text{complex, often hybridized skill sets})$
 - 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

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

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

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.

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

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)

Identify scientific questions that are potentially testable clinical research hypotheses. (1.2)

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

Maintain awareness of new technologies, methodologies and techniques which enhance the conduct, safety and validity of the clinical study. (1.4)

Critically analyze clinical study results. (1.5)

CDS 6010 CDS 6020 CDS 6030 CDS 6050

BE 7036

PHDD 8010

CDS 7000

CDS 7020

CS 7053

PHIL 6050

w 1

w1

w1

w2

w2

w1

w 2

w2

w2

w2-4,6,7

w 11

w2

W2

w2

w 13

w 12

w6

w8,13

w 5,9,13

w10,12

w6,7,13, 14

w14,15

w1,3,8-14

w11

w 11

Data Management and Informatics (Domain 6)

Describe the role and importance of statistics and informatics in clinical studies. (6.1)

Describe the origin, flow, and management of data through a clinical study. (6.2)

Describe the best practices and resources required for standardizing data a collection, capture, management, analysis, and reporting. (6.3)

Describe, develop, and implement processes for data quality assurance. (6.4)

w4

w1

w1

w 5,6

w4,5

w15

w4

w5,9,15

w2,3

w 10

w2,3

w4

w5,9

w7

w5

Methodology (cont'd)

Mapping of ASA DSP Skills Areas to CDS Courses

Draft Date: 30 Jul 25

Data Privacy and Stewardship

Ensuring protection of personal and sensitive data
Managing loss of sensitive data
Data stewardship and standards

Core Courses			
CDS 6010	CDS 6020	CDS 6030	CDS 6050

Research Courses				
BE 7036	CDS 7000	CDS 7020	CS 7053	PHIL 6050

w10						w2,3,8	w11
	w 6, 12-13		w6	w8			
w10, 12						w7	

Definition, Acquisition, Engineering, Architecture, Storage and Curation

Data collection and management
Data engineering
Deployment

w2-8	w2-4		w4				w2-4
w7-8	w7	w8	w4	w4	w9-10		w5
		w12-14					

Problem Definition and Communication with Stakeholders

Problem definition
Relationship management

		w1		w2			
w15		w15	w8	w16		w15-16	w15

Problem Solving, Analysis, Statistical Modeling, Visualization

Identifying and applying technical solutions and project management
Data preparation and feature modeling
Data analysis and modeling building

	w10-11	w3-4			w2-4		
w12					w9-11	w6,8,9	
	w9	w13-14			w12-14		

Evaluation and Reflection

Project evaluation
Ethical behavior
Sustainability and best practices
Reflective practice and ongoing development

	w9		w8			w5-6	
				w1		w7	w1-12
w1			w2				
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	

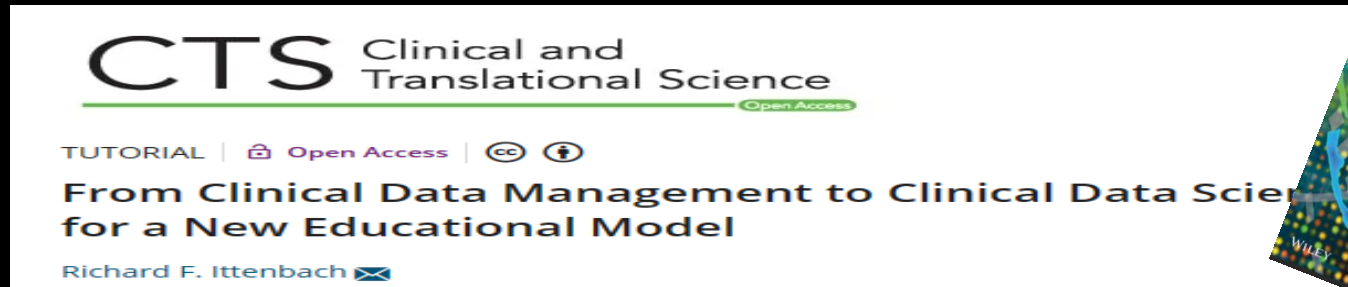
Note . * Denotes core content.

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

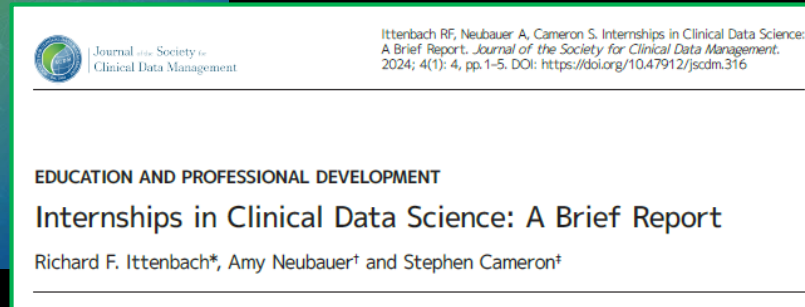
Clinical Data Science Curriculum Key Attributes

- 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

Further Reading





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



14

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

Richard F. Ittenbach¹ , Brian McCourt²  and Maurizio Macaluso¹

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

15



References

1. 21 U.S. Code 301. Federal Food, Drug, and Cosmetic Act. Washington, DC: U.S. Government Printing Office.; 1938 Ch. 675, Sec.1, 52 Stat. 1040.
2. Greene JA, Podolsky SH. Reform, regulation, and pharmaceuticals—the Kefauver–Harris Amendments at 50. *The New England Journal of Medicine*. 2012;367(16):1481.
3. Meadows M. Promoting safe and effective drugs for 100 years. *FDA Consumer Magazine*. 2006;40(1)
4. Ittenbach, R. F. *Clinical and Translational Science*, 16(8), 1340-1351.
5. U.S. Department of Labor. *Clinical Data Manager: 15-2051.02*. 2025. <https://www.onetonline.org/link/summary/15-2051.02> (accessed July 29, 2025)
6. Boichuk V, Glushakov S. The untapped potential of clinical data management in Ukraine: a novel training program case study. *J Soc Clin Data Manag*. 2021;1(3):1-4. doi:10.47912/jscdm.43
7. Houston L, Probst Y. Clinical data management: a review of current practices in Australia. *J Soc Clin Data Manag*. 2021;1(3):1- 5. doi:10.47912/jscdm.62
8. Yamaguchi T, Miyaji T, Suganami H, Hayashi Y, Committee SJS. Clinical data management in Japan: past, present, and future. *J Soc Clin Data Manag*. 2021;1(3):1-6. doi:10.47912/jscdm.45
9. Banach MA, Fendt KH, Proeve J, Plummer D, Qureshi S, Limaye N. Clinical data management in the United States: where we have been and where we are going. *J Soc Clin Data Manag*. 2021;1(1):14,1-6. doi:10.47912/jscdm.61
10. Valenta AL, Berner ES, Boren SA, et al. AMIA Board White Paper: AMIA 2017 core competencies for applied health informatics education at the master's degree level. *Journal of the American Medical Informatics Association*. 2018;25(12):1657-1668.
11. Joint Task Force for Clinical Trial Competency. Domains and Leveled Core Competencies. Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. Accessed March 6, 2022, 2022. <https://mrctcenter.org/clinical-trial-competency/framework/domains/>
12. Sonstein SA, Jones CT. Joint task force for clinical trial competency and clinical research professional workforce development. *Frontiers in Pharmacology*. 2018;1148.
13. Zozus MN, Lazarov A, Smith LR, et al. Analysis of professional competencies for the clinical research data management profession: implications for training and professional certification, *Journal of the American Medical Informatics Association*. 2017;24(4):737-745.
14. Ittenbach R, Neubauer A, Cameron S, Ittenbach RF. Internships in Clinical Data Science: A Brief Report. *Journal of the Society for Clinical Data Management*. 2024 Jun 6;4(2).
15. Ittenbach RF, McCourt BJ, Macaluso M. Empowering professionals: An intensive short course on fundamentals of clinical data science. *Journal of Clinical and Translational Science*. 2025 Oct 1:1-25.

Thank you

Questions/Correspondence:
Rick Ittenbach (richard.ittenbach@cchmc.org)