

Building for the Future:

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



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

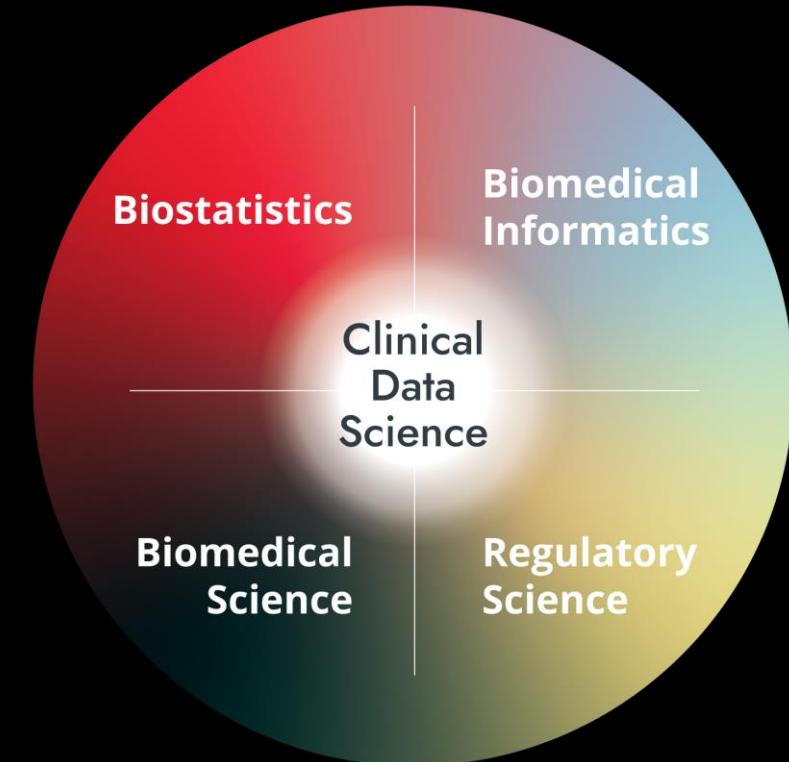


Purpose

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 (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 or Global Regulatory Drugs/Devices ^c	BE 7036 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

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CDS 6010	CDS 6020	CDS 6030	CDS 6050	BE 7036	PHDD 8010	CDS 7000	CDS 7020	CS 7053	PHIL 6050
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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

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Data Privacy and Stewardship

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

Core Courses				Research Courses				
CDS 6010	CDS 6020	CDS 6030	CDS 6050	BE 7036	CDS 7000	CDS 7020	CS 7053	PHIL 6050

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

Definition, Acquisition, Engineering, Architecture, Storage and Curation

Data collection and management
Data engineering
Deployment

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

Problem Definition and Communication with Stakeholders

Problem definition
Relationship management

w15 w1
w15 w8 w2
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
w12 w9 w13-14
w2-4 w9-11 w12-14
w6,8,9

Evaluation and Reflection

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

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

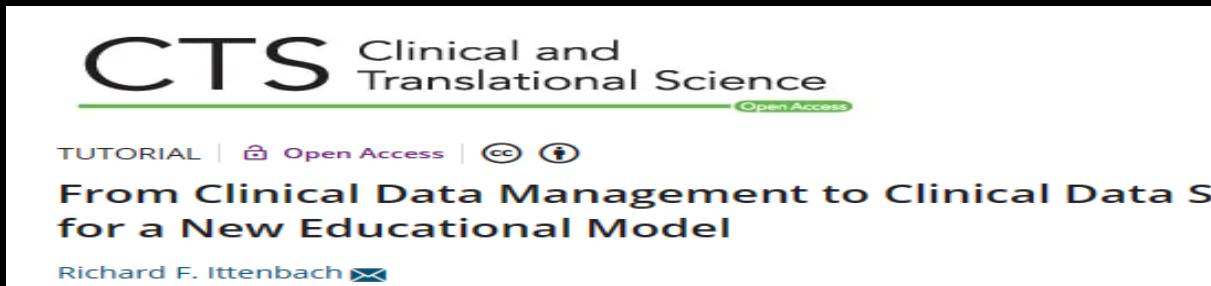
Source: Ittenbach et al. *J Clin & Trans Sci*, in press



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



CTS Clinical and Translational Science
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From Clinical Data Management to Clinical Data Science for a New Educational Model
Richard F. Ittenbach 



JOURNAL OF THE SOCIETY FOR CLINICAL DATA MANAGEMENT
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†

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

Richard F. Ittenbach¹ , Brian McCourt²  and Maurizio Macaluso¹

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Thank you

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