

Degree Proposal

Master of Science in Real World Evidence in Healthcare and Life Sciences

Bouvé College of Health Sciences in partnership with the OHDSI Center at Northeastern

Department of Health Sciences

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Executive Summary

In January 2021, Provost David Madigan in partnership with Michael Pollastri, Senior Vice Provost, Academic Lead at the Roux Institute set out to explore how Northeastern University's world class expertise in experiential learning could facilitate the advancement of open science. Madigan, a longtime research leader in the Observational Health Data Sciences and Informatics (OHDSI) community, initiated the launch of a dedicated center ("The OHDSI Center") to establish Northeastern's commitment to this worldwide multi-stakeholder, interdisciplinary collaborative to extract the value of health data through large-scale analytics.

Through a series of ongoing stakeholder interviews, partnership meetings, market analysis and learner testimonials, it became evident that Northeastern University is well positioned to offer an innovative, first-in-market, professional master's program to credential learners interested in developing their acumen in the generation of evidence from routinely collected health data (e.g. electronic health records and insurance claims). This program will enable Northeastern to make a global impact in a bustling, open science movement that provides in-demand skills.

Rooted in open, reproducible science, the Master of Science in Real World Evidence (RWE) in Healthcare and Life Sciences is a multi-faceted educational offering that gives learners practical knowledge into the breadth and depth of real world data and a rich understanding of non-interventional studies. Housed in the Department of Health Sciences and the Roux Institute, learners will explore how observational research produces a comprehensive understanding of disease including experience with appropriate methods and software to conduct this research.

RWE is the clinical evidence regarding the usage and potential benefits, or risks of a medical product derived from analysis of real-world data. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, pragmatic trials, and observational studies. Real-world *data* (RWD) are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources, for example: Electronic health records, claims and billing activities.

RWD and RWE are playing an increasing role in health care decisions. The FDA uses RWD and RWE to monitor postmarket safety and to make regulatory decisions. The health care community uses these data to support coverage decisions and to develop guidelines and decision support tools for clinical practice. Medical product developers use RWD and RWE to support clinical trial designs and observational studies to generate innovative, new treatment approaches.

Market Demand

While there is significant saturation in the educational marketplace around healthcare analytics, informatics and data science, this program strategically addresses a critical gap in the learning space: the specific needs of pharmaceutical companies and healthcare systems to use a network of federated secondary healthcare datasets to answer clinical questions at scale aimed at reproducibility and repeatable science that will improve patient outcomes. Our team conducted stakeholder interviews with the world's leading pharmaceutical companies. Each company expressed frustration around the lack of skilled talent with expertise to scale their RWD strategy and RWE teams. There are currently more than 1500 open job postings on LinkedIn tagged to the term "real world evidence" and 9500 open jobs tagged to "real world data." Hiring managers have expressed a significant gap in the available talent to fill these roles. Some universities offer ad-hoc workshops or massive-open online courses (MOOCs) to acclimate learners to these concepts. There are no other comparable programs that coordinate an immersive master's level training that covers the range of topics that the workforce expects these learners to have expertise in.

We anticipate this curriculum proposed herein could be modular, stackable units that can be reused across a variety of learner audiences in Northeastern's community. Our timeline is to pursue approval for launch in the 2022-2023 academic year beginning by obtaining department approval in late September. We welcome input on how to ensure that this proposal builds on the rich existing curricula and expertise within the Northeastern community.

Resources

Northeastern has already made a significant investment in Bouvé College of Health Sciences Department of Health Sciences and the Roux Institute. There are 2 part-time Professor of Practice faculty (non-tenure-track) in Bouvé College of Health Sciences, 2 full-time faculty (tenure-track) in the Department of Health Sciences and 2 full-time staff at the Roux Institute with interest in serving as adjunct faculty to support this curriculum. Additional faculty lines in research areas related to RWE are already part of the strategic plan of the Bouvé College of Health Sciences Department of Health Sciences and the Roux Institute.