

Assessment of Real-World Evidence Research Competencies in Federated Research Networks: A Maternal Health Fellowship Program Evaluation

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Background

The increasing adoption of real-world evidence (RWE) generated from observational healthcare data has expanded opportunities for large-scale, distributed research across federated data networks^{1,2}. The Observational Health Data Sciences and Informatics (OHDSI) community has demonstrated the value of standardized data models, open-source analytics, and collaborative research approaches for generating reproducible evidence from diverse healthcare databases^{3,4,5}. However, conducting high-quality RWE studies in federated networks requires competencies that extend beyond traditional clinical research training, including expertise in standardized data models, data governance, distributed analytics, protocol development, and interdisciplinary collaboration. Despite growing demand for RWE researchers, standardized frameworks for defining and assessing competencies specific to federated RWE research remain limited. This study aimed to develop and evaluate a competency assessment framework tailored to RWE studies using the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) and distributed research networks.

Methods

The Joint Task Force (JTF) Core Competency Framework for Clinical Research Professionals was adapted to develop a competency framework for RWE research using the OMOP CDM and federated research networks (Table 1). Through iterative expert review, four new domains were added: Ethnicity and Governance, Protocol Development, Study Operations, and Data Analysis and Informatics. Four original JTF domains were retained and modified. Participants from academic, clinical, and data science backgrounds completed pre- and post-training self-

assessments using a 10-point competency scale. Changes in competency scores were evaluated using paired t-tests and effect size estimates.

Table 1. Mapping of JTF Clinical Research Competencies to RWE Research Competency Domains

JTF Domain	JTF Key Elements	RWE Research Domain	RWE Research Key Elements
1. Scientific Concepts and Research Design	• Clinical research hypotheses from literature • Statistical, epidemiological, operational study design • Therapeutic and comparative effectiveness	1. Scientific Concepts and Research Design	• Research questions suitable for RWE studies • Real-world data availability assessment • Target/comparator/outcome cohorts using standardized tools • Real-world effectiveness and population health
2. Ethical and Participant Safety Considerations	• Human subject protection (national/international) • Privacy regulations across phases • Vulnerable populations and safeguards	2. RWE Research Ethics and Governance	• Multi-institutional EHR databases protection • Data governance across institutions • Regulatory compliance for RWE research
3. Investigational Products Development and Regulation	• Medicine development process • Roles of institutions in drug development • Regulatory pathways	3. RWE Research Protocol Development	• Clear research questions for cross-institutional work • Computable phenotypes using standardized data • Analysis plans with appropriate statistical methods • Protocol components for RWE studies
4. Clinical Study Operations (Good Clinical Practice)	• Clinical trials within development plan • Clinical investigation team roles (GCP) • Monitoring processes	4. RWE Study Operations	• Multi-institutional studies within OHDSI framework • RWE research team roles (OHDSI guidelines) • Collaborative platforms and version control
5. Study and Site Management	• Financial, timeline, personnel management • Risk management and quality improvement • Patient recruitment and progress tracking	5. Study and Site Management	• Timeline and personnel for multi-institutional studies • Risk management and quality in RWE research • Progress tracking in collaborative networks

	• Biostatistics and informatics role • Data flow in clinical trials • Electronic data capture (EDC) • Data quality assurance and SOPs		• Data transformation, CDM harmonization, and understanding of data quality • Open-source tools for data harmonization • Statistical methods for large-scale analyses • Cohort generation and standardized analytical frameworks • Reproducibility across multi-institutional networks
6. Data Management and Informatics		6. Data Analysis and Informatics	
	• Leadership, management, mentorship principles • Professional guidelines and ethics codes		• Leadership for RWE research teams • Ethics in collaborative networks
7. Leadership and Professionalism		7. Leadership and Professionalism	
	• Sponsor-CRO-site communication • Communication to colleagues and public		• Study leads, data partners, OHDSI collaborators • Communication to clinicians and public • RWE research findings dissemination
8. Communications and Teamwork		8. Communication and Teamwork	

Note: JTF = Joint Task Force for Clinical Trial Competency; RWE = Real-World Evidence; SOP = Standard Operating Procedures; CRO = Contract Research Organization; RWD = Real-World Data; OMOP = Observational Medical Outcomes Partnerships; OHDSI = Observational Health Data Sciences and Informatics; EHR = Electronic Health Record; GCP = Good Clinical Practice; CDM = Common Data Model

Result

An eight-domain competency framework was developed to encompass the methodological, operational, and collaborative skills required for conducting RWE studies using standardized healthcare data and federated research networks. Application of the framework demonstrated its ability to assess competencies across diverse professional backgrounds and capture variation in self-reported proficiency across domains. Following training, competency scores increased across all eight domains, with an average improvement of 2.5 points and statistically significant gains observed throughout (Table 2). The largest increase was observed in Leadership and Professionalism (mean increase 3.66; 95% CI, 2.69–4.62).

Table 2. Average Self-Assessed Competency Scores Before and After the Program by Domain

Domain	N	Pre-training score Mean (SD)	Post-training score Mean (SD)	Change (95% CI)	p-value	Cohen's d
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1. Scientific Concepts and Research Design	17	3.25 ± 2.10	6.61 ± 1.88	3.35 (2.38, 4.32)	<0.001 ***	1.78
2. RWE Research Ethics and Governance	17	5.88 ± 1.98	7.84 ± 1.32	1.96 (1.27, 2.65)	<0.001 ***	1.45
3. RWE Research Protocol Development	17	5.96 ± 2.44	7.88 ± 1.30	1.92 (1.05, 2.79)	<0.001 ***	1.13
4. RWE Study Operations	17	2.82 ± 2.00	5.04 ± 1.94	2.22 (1.45, 2.98)	<0.001 ***	1.49
5. Study and Site Management	17	2.96 ± 2.43	5.22 ± 2.34	2.25 (1.43, 3.08)	<0.001 ***	1.4
6. Informatics and Data Analysis	16	2.41 ± 1.49	5.79 ± 1.76	3.38 (2.49, 4.26)	<0.001 ***	2.04
7. Leadership and Professionalism	16	2.09 ± 1.53	5.75 ± 1.95	3.66 (2.69, 4.62)	<0.001 ***	2.03
8. Communications and Teamwork	16	4.56 ± 2.15	6.97 ± 1.49	2.41 (1.43, 3.38)	<0.001 ***	1.32

Note: N = Number of Respondents; RWE = Real-World Evidence; Scores based on 0-10 scale where 0 = little knowledge and 10 = high proficiency; Paired t-tests used; Cohen's d shows effect size. *** p<0.001

Conclusion

A competency assessment framework was developed and evaluated for RWE research conducted using standardized healthcare data and federated research networks. The framework demonstrated the ability to assess competency development and identify methodological knowledge gaps across key domains of RWE research. These findings suggest that competency-based assessment may support workforce development, training program evaluation, and capacity building for large-scale OHDSI and OMOP-based RWE research initiatives.

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