

MedValence: A Distributed Methodological Framework for Developing and Validating Personalized Prediction Models of Drug Efficacy and Safety Using Real-World Data

Background:

- With the rapid growth in availability and scale of real-world data (RWD), clinical decision support is increasingly shifting from population-average analyses toward individualized, patient-centered predictive applications.
- However, most existing multi-institutional or multinational observational studies continue to focus on population-level associations or average treatment effect estimates, providing limited support for individualized prediction of drug efficacy and safety in real-world clinical settings.
- Clinicians and policy makers require predictive models that can generate patient-level outcome estimates while demonstrating robustness, reproducibility, and transportability across heterogeneous healthcare systems.

Figure 1. MedValence Distributed Workflow for Personalized Prediction Model Development and Validation

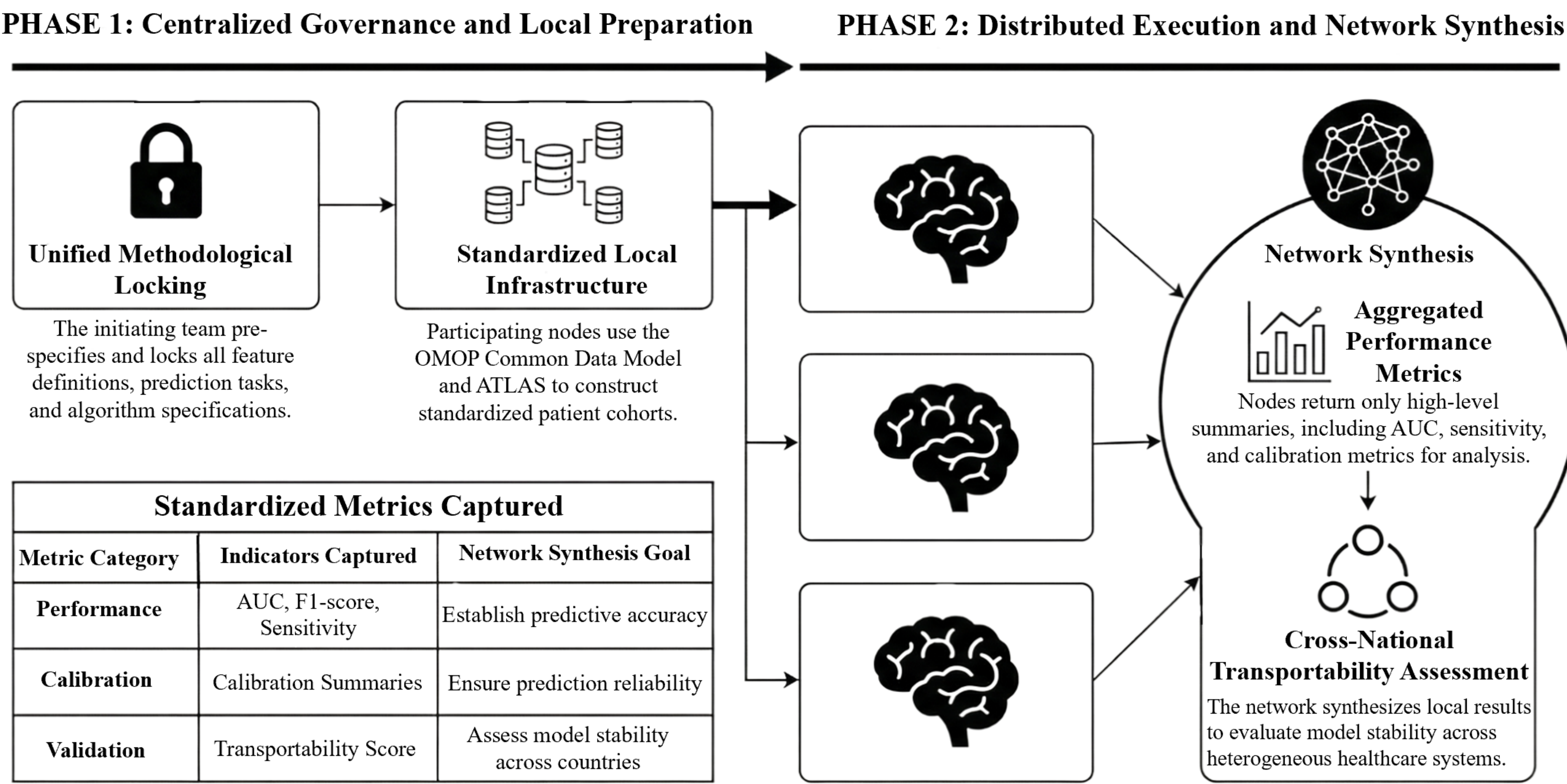


Table 1. Cross-National, Multi-Center Performance and Transportability of Drug-Specific Prediction Models

Category	Endpoint	Data node (country / center)	Sample size (N)	AUC	Sensitivity	Specificity	F1-score	Calibration	Transportability
Efficacy	Endpoint A	Site A (Country 1)							
		Site B (Country 2)							
		Site C (Country 3)							
		Network summary	—	Median (range)	—	—	—	Overall stable	High
	Endpoint B	Site A (Country 1)							
Safety	Endpoint A	Site B (Country 2)							
		Site C (Country 3)							
		Network summary	—	Median (range)	—	—	—	Overall stable	High
	Endpoint B	Site A (Country 1)							
		Site B (Country 2)							
		Site C (Country 3)							
		Network summary	—	Median (range)	—	—	—	Overall stable	High
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