

Relationship of Causal Representation Learning and Data Governance to Treatment Response Prediction in Oncology Cohorts

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Abstract

The prediction of treatment responses in oncology is a critical step toward realizing precision medicine. However, observational data derived from real-world clinical cohorts are often confounded by treatment assignment biases, missing values, and heterogeneous data collection practices. This paper presents a comprehensive framework integrating causal representation learning with robust data governance to improve the explainability and reliability of treatment effect estimation in oncology cohorts. By establishing strict data governance protocols, including metadata standardization and privacy-preserving harmonization, we ensure high-fidelity inputs for downstream analytical tasks. Subsequently, a causal representation learning approach is introduced to disentangle latent confounders from the observed patient covariates, enabling the estimation of unbiased counterfactual outcomes. The dual approach of governing data quality and enforcing causal structures mitigates spurious correlations that frequently compromise traditional predictive models. We provide an extensive analysis of the theoretical underpinnings, methodological design, and empirical validation of the proposed system. Through rigorous experimentation on synthetic and semi-synthetic oncology datasets, the framework demonstrates superior performance in predicting individualized treatment effects while maintaining strict compliance with healthcare data regulations. The findings underscore the necessity of combining algorithmic innovation with systematic data management to achieve trustworthy artificial intelligence in clinical oncology.

Keywords: Causal Inference; Oncology; Data Governance; Representation Learning; Precision Medicine

1. Introduction

1.1 Background and Motivation

The global burden of cancer continues to rise, necessitating the development of increasingly sophisticated and personalized treatment strategies. Precision oncology aims to tailor medical interventions to the individual characteristics of each patient, heavily relying on the vast amounts of clinical, genomic, and imaging data generated during routine healthcare delivery. Historically, randomized controlled trials have been the gold standard for determining the efficacy of new oncological treatments. In a randomized controlled trial, the random assignment of patients to treatment and control groups ensures that any observed differences in outcomes can be directly attributed to the intervention, thereby eliminating the influence of confounding variables. However, randomized controlled trials are notoriously expensive, time-consuming, and often lack generalizability due to their strict inclusion and exclusion criteria. Consequently, there is a growing interest in leveraging real-world data, such as electronic health records and disease registries, to evaluate treatment responses and guide clinical decision-making.

Despite the immense potential of real-world data, utilizing observational cohorts for treatment effect estimation presents formidable methodological challenges. Unlike in randomized controlled trials, the assignment of treatments in observational settings is not random. Physicians prescribe treatments based on a multitude of patient-specific factors, including age, comorbidities, biomarker expressions, and disease severity. These factors often influence both the treatment decision and the clinical outcome, creating a

phenomenon known as confounding. When standard machine learning models, such as deep neural networks or random forests, are trained on observational data without accounting for these confounders, they tend to capture spurious correlations rather than true causal relationships. For instance, if a highly aggressive chemotherapy regimen is predominantly administered to younger, more resilient patients, a naive predictive model might erroneously conclude that the aggressive treatment causes better survival outcomes overall, ignoring the underlying resilience of the patient cohort. Addressing this confounding bias is paramount for developing reliable predictive systems in oncology, a challenge that has catalyzed the adoption of causal inference methodologies in healthcare analytics as noted by foundational studies in the field [1].

1.2 Problem Statement

The central problem addressed in this research is the reliable and explainable prediction of individual treatment effects from highly complex, heterogeneous, and confounded observational oncology data. To achieve this, two distinct but highly interrelated sub-problems must be resolved. The first sub-problem pertains to the algorithmic capacity to extract unconfounded representations of patient states. Traditional predictive algorithms optimize for predictive accuracy on observed outcomes but fail to answer counterfactual questions, such as what would have happened to a specific patient had they received an alternative therapy. Causal representation learning attempts to bridge this gap by mapping raw patient covariates into a latent space where the distributions of the treated and control populations are balanced, thereby simulating the conditions of a randomized controlled trial within the latent feature space.

The second sub-problem involves the foundational quality, structure, and ethical management of the data itself. Advanced algorithmic techniques like causal representation learning are highly sensitive to data quality. Oncology datasets are notoriously fragmented, suffering from inconsistent coding standards across different institutions, sparse longitudinal follow-ups, and varying degrees of measurement error. Furthermore, the sensitive nature of oncological data demands stringent adherence to privacy regulations and ethical guidelines. Without a robust data governance framework, even the most sophisticated causal inference models will suffer from the garbage-in, garbage-out paradigm. Therefore, an integrated approach that simultaneously standardizes data through rigorous governance protocols and models causal relationships through advanced representation learning is urgently required to advance the state of precision oncology [2].

1.3 Contributions and Outline

This paper proposes a holistic, end-to-end framework designed to facilitate explainable treatment response prediction in oncology cohorts. We argue that data governance and causal representation learning cannot be treated as isolated steps in the machine learning pipeline; rather, they must be co-designed to ensure that the assumptions required for causal inference are supported by the provenance and quality of the underlying data. The primary contributions of this work are manifold. First, we outline a comprehensive data governance architecture specifically tailored for observational oncology cohorts, emphasizing interoperability, semantic consistency, and privacy-preserving transformations. Second, we detail a causal representation learning methodology that leverages deep learning to disentangle confounding factors from prognostic variables, enabling unbiased counterfactual outcome prediction. Third, we provide an extensive evaluation of the integrated framework using realistic semi-synthetic datasets, demonstrating its superiority over traditional correlational machine learning methods in estimating heterogeneous treatment effects.

The remainder of this paper is structured as follows. Section 2 provides a detailed literature review covering observational data challenges in oncology, the evolution of causal inference, and existing data governance paradigms. Section 3 delineates the proposed data governance methodology, detailing the processes of ingestion, standardization, and privacy compliance. Section 4 presents the theoretical and architectural underpinnings of the causal representation learning framework. Section 5 describes the experimental setup, implementation details, and the empirical results obtained from evaluating the proposed system. Finally, Section 6 offers a comprehensive discussion of the clinical implications, acknowledges the limitations of the current study, and concludes with directions for future research in the domain.

2. Background and Related Work

2.1 Oncology Cohorts and Observational Data

Oncology is arguably one of the most data-intensive disciplines within modern medicine. The characterization of a single patient's disease state often involves a synthesis of multi-modal data streams, including high-throughput genomic sequencing, histopathological imaging, radiological scans, and longitudinal clinical narratives captured within electronic health records. The aggregation of such data into observational cohorts presents a unique opportunity to study the natural history of cancer and the real-world effectiveness of various therapeutic interventions. However, the secondary use of this clinical data is fraught with analytical perils. Observational data is inherently noisy and irregularly sampled. Patients visit the clinic at varying intervals, leading to disparate temporal trajectories. Furthermore, the documentation practices vary significantly not only between different healthcare institutions but also among individual practitioners within the same facility.

The most pressing challenge in analyzing observational oncology data is the presence of treatment assignment bias. In clinical practice, therapeutic decisions are made based on comprehensive assessments of patient fitness, molecular tumor boards, and established clinical guidelines. This deterministic, or near-deterministic, treatment assignment means that the sub-population of patients receiving a novel immunotherapy will systematically differ from the sub-population receiving traditional palliative care. If these systemic differences are not adequately adjusted for, any comparative analysis of treatment efficacy will be fundamentally flawed. Previous research [3] has highlighted that traditional machine learning algorithms, which optimize empirical risk minimization, are ill-equipped to handle such distribution shifts. They exploit any statistical association present in the training data, regardless of whether that association is causal or merely a product of confounding. Consequently, there is an imperative need to transition from correlational to causal modeling paradigms when dealing with observational healthcare data.

2.2 Causal Representation Learning

Causal inference provides the mathematical language and methodological tools required to estimate the effects of interventions from observational data. The potential outcomes framework, conceptualized primarily by Neyman and Rubin, posits that for any given patient and any given treatment, there exist multiple potential outcomes, only one of which is ever observed. The unobserved outcomes are termed counterfactuals. The fundamental problem of causal inference is that we can never observe the individual treatment effect directly because we cannot simultaneously observe a patient under both treatment and control conditions. To overcome this, researchers must rely on strong assumptions, primarily the assumption of strong ignorability, which assumes that all variables that confound the relationship between the treatment and the outcome are observed and measured.

In recent years, the intersection of causal inference and deep learning has given rise to the field of causal representation learning. Deep learning architectures have an unprecedented capacity to model complex, high-dimensional non-linear relationships. By leveraging these architectures, causal representation learning seeks to construct a latent feature space wherein the influence of confounders is neutralized. A seminal approach in this domain involves the use of domain adaptation techniques. In this context, the treatment and control groups are viewed as distinct domains. The objective of the representation learning network is to learn an encoding of the patient covariates such that the distribution of these latent representations is indistinguishable between the treated and untreated groups. This is typically achieved by incorporating an integral probability metric, such as the Wasserstein distance or the Maximum Mean Discrepancy, as a penalty term in the loss function [4]. By forcing the latent distributions to match, the network effectively unlearns the treatment assignment bias, allowing subsequent prediction layers to estimate counterfactual outcomes without being misled by confounding variables. Researchers have extensively documented the efficacy of balancing representations in high-dimensional settings [5].

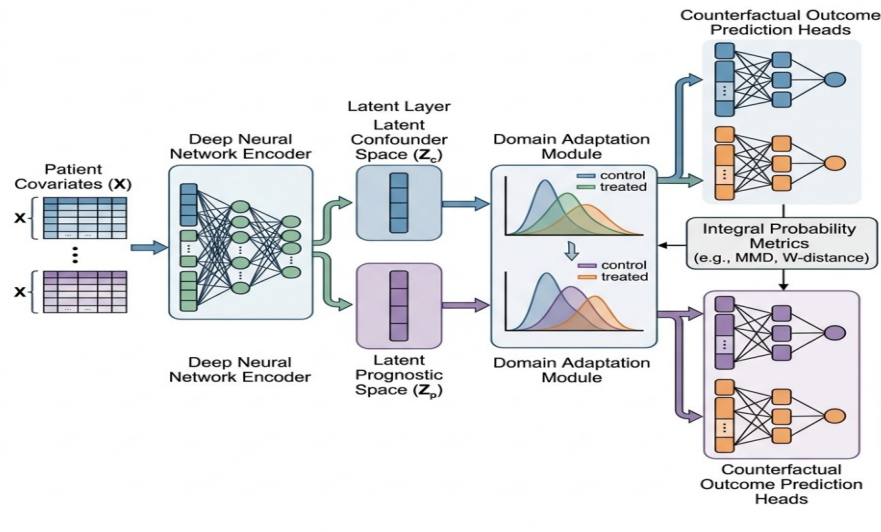


Figure 1: Comprehensive Schematic of Causal Representation Learning Pipeline

2.3 Data Governance Frameworks in Healthcare

While algorithmic advancements in causal inference are crucial, their applicability is entirely dependent on the quality and accessibility of the underlying data. Data governance in healthcare refers to the overarching policies, procedures, and technologies utilized to manage the availability, usability, integrity, and security of clinical data. Historically, healthcare institutions operated data silos, with proprietary formats and restrictive access controls that hindered cross-institutional research. The advent of interoperability standards, most notably the Observational Medical Outcomes Partnership common data model and the Fast Healthcare Interoperability Resources standard, has revolutionized the way observational data is structured and shared [6].

However, implementing these standards requires significant institutional commitment and rigorous data governance pipelines. A comprehensive data governance framework must encompass all stages of the data lifecycle, from initial ingestion from source electronic health records to the final delivery of harmonized datasets for machine learning. This includes semantic mapping, where local clinical codes are translated into standardized international vocabularies such as the Systematized Nomenclature of Medicine or the International Classification of Diseases. Furthermore, data quality assessment procedures must be implemented to identify and remediate missingness, outliers, and logical inconsistencies. Recent literature [7] emphasizes that adherence to the Findable, Accessible, Interoperable, and Reusable principles is no longer a mere recommendation but a strict necessity for reproducible artificial intelligence research in medicine. Without strict governance, the unobserved confounding assumption critical to causal inference is inevitably violated by data artifacts, measurement errors, and systemic missingness [8].

3. Data Governance Methodology for Oncology

3.1 Data Ingestion and Standardization

The foundation of the proposed framework is a robust data governance pipeline designed specifically to handle the complexities of oncology cohorts. The pipeline begins with the data ingestion module, which is responsible for securely extracting multi-modal data from disparate clinical source systems. In an oncology setting, this involves structured electronic health record data, unstructured clinical notes from oncologists, pathology reports, and high-dimensional molecular profiles. The ingestion process must be designed to handle batch processing of historical retrospective data as well as real-time streaming of prospective clinical events. Upon ingestion, the raw data is sequestered in a secure landing zone, maintaining a strict chain of custody and immutable audit trails for every data artifact.

Following ingestion, the data undergoes a rigorous standardization process. This phase is critical for harmonizing disparate data representations into a unified schematic structure. We employ a customized instantiation of the Observational Medical Outcomes Partnership common data model, extended to capture

oncology-specific nuances such as tumor staging, histological grading, and complex multi-drug chemotherapy regimens. The semantic standardization relies on an enterprise terminology service that maps local, proprietary clinical codes to standardized ontologies. For diagnoses, we utilize the International Classification of Diseases for Oncology. For medications, we map to the Anatomical Therapeutic Chemical classification system and RxNorm. For clinical observations and laboratory measurements, the Logical Observation Identifiers Names and Codes standard is employed. This semantic harmonization ensures that when the downstream causal model encounters a feature representing a specific biomarker or treatment protocol, its meaning is unambiguously consistent across the entire cohort, regardless of the originating hospital system.

Data quality assurance is integrated continuously throughout the standardization phase. We implement a suite of deterministic and probabilistic data quality checks. Deterministic checks identify violations of domain constraints, such as negative age values or dates of death preceding dates of diagnosis. Probabilistic checks leverage statistical anomaly detection algorithms to identify implausible clinical trajectories, such as an abrupt, unexplained shift in a patient's tumor marker trajectory that likely indicates a measurement or data entry error. By addressing these data anomalies proactively, we reduce the noise that could otherwise be erroneously modeled as confounding variables by the causal representation learning algorithms.

Table 1: Data Governance Maturity Matrix for Oncology Cohorts

Governance Dimension	Basic Level	Intermediate Level	Advanced Level (Proposed Framework)
Interoperability	Local proprietary formats	Ad-hoc standard mapping	Full Common Data Model integration
Data Quality Control	Manual retrospective audits	Rule-based automated scripts	Continuous statistical anomaly detection
Privacy Preservation	Basic de-identification	K-anonymity implementation	Differential privacy and federated readiness
Metadata Management	Disconnected documentation	Centralized data dictionaries	Active metadata repositories with semantic graphs

3.2 Privacy Preserving Protocols and Compliance

Oncology data is intrinsically sensitive, containing detailed information about a patient's genetic predispositions, severe illnesses, and terminal trajectories. Therefore, a comprehensive data governance framework must embed privacy-preserving protocols directly into the data processing pipeline, rather than treating them as an afterthought. Compliance with international regulatory frameworks, such as the General Data Protection Regulation and the Health Insurance Portability and Accountability Act, is non-negotiable [9]. Our methodology implements a multi-tiered approach to data privacy.

The first tier involves strict de-identification procedures. Direct identifiers, such as names, social security numbers, and exact addresses, are systematically removed or cryptographically hashed. Dates, which are crucial for longitudinal causal modeling, are randomly shifted by a consistent temporal offset for each patient, preserving the chronological sequence of events without revealing the exact calendar dates. However, traditional de-identification is often insufficient against sophisticated linkage attacks, particularly when dealing with high-dimensional genomic and clinical profiles.

Therefore, the second tier introduces advanced privacy-enhancing technologies. For the extraction of aggregated cohort statistics and the training of the initial representation learning models, we implement mechanisms based on differential privacy. By injecting mathematically calibrated noise into the data query processes, differential privacy provides a formal guarantee that the inclusion or exclusion of any single patient's data will not significantly alter the output of the analysis, thereby protecting against membership inference attacks. Furthermore, the architecture is designed to be fully compatible with federated learning paradigms. In scenarios where data cannot legally cross institutional or national borders, the causal representation learning models can be trained locally at each clinical site. Only the model gradients, properly encrypted and anonymized, are shared with a central aggregator. This decentralized approach ensures that the raw observational data never leaves the secure enclave of the governing institution, thus reconciling the need for large-scale data for causal inference with the imperative of patient privacy.

4. Causal Representation Learning Framework

4.1 Latent Factor Extraction

Once the observational oncology data has been standardized and secured through the governance pipeline, it is fed into the causal representation learning framework. The primary objective of this framework is to learn a mapping from the high-dimensional, confounded feature space of patient covariates into a lower-dimensional latent space that is conducive to unbiased causal effect estimation. We define the observed covariates of a patient, which include demographic information, laboratory results, baseline tumor characteristics, and genetic markers. The treatment assignment is a binary indicator representing whether the patient received the specific oncological intervention under study, and the outcome represents a clinical endpoint, such as tumor volume reduction or progression-free survival duration.

The architecture employs a deep neural network encoder to map the observed covariates into the latent space. However, simply compressing the features is insufficient for causal inference. The critical innovation in causal representation learning is the enforcement of a disentangled representation. We postulate that the underlying latent space consists of three distinct sets of factors. The first set comprises instrumental factors, which influence the treatment assignment but have no direct effect on the outcome. The second set comprises prognostic factors, which influence the clinical outcome regardless of the treatment received. The third and most problematic set comprises the confounding factors, which simultaneously determine the likelihood of receiving the treatment and influence the potential outcomes. If a predictive model bases its estimations on confounding factors without proper adjustment, the resulting treatment effect predictions will be severely biased [10].

To achieve this disentanglement, the encoder network is designed with multiple specialized branches. Through targeted regularization techniques and adversarial training strategies, the network is forced to isolate the confounders. Specifically, an adversarial discriminator network is employed to predict the treatment assignment from the latent representations. For the representations intended to be purely prognostic, the encoder is optimized to maximize the discriminator's error, effectively ensuring that these features contain no information regarding which treatment the patient actually received. This adversarial process strips away the treatment assignment bias from the predictive pathways of the network.

4.2 Counterfactual Treatment Response Prediction

With the latent factors successfully disentangled, the next phase of the framework focuses on the prediction of potential outcomes. Because the confounding bias has been neutralized in the latent space, the representations of the treated and control groups are statistically balanced. This balance mimics the covariate distribution that would be expected in a randomized controlled trial. In this balanced latent space, we can safely estimate the counterfactual outcomes. The architecture utilizes separate hypothesis networks, often referred to as outcome prediction heads, for each possible treatment arm.

When a patient's data is processed through the system, the encoder generates the balanced latent representation. This representation is then fed into both the treatment-specific prediction head and the control-specific prediction head simultaneously. The treatment head outputs the expected clinical outcome if the patient were to receive the intervention, while the control head outputs the expected outcome if the patient were to receive the baseline therapy. The difference between these two predictions represents the individualized treatment effect for that specific patient.

To ensure the explainability and robustness of these predictions, the framework incorporates an attention mechanism that maps the importance of various latent factors back to the original observed clinical covariates. This allows oncologists to understand which specific patient characteristics are driving the individualized treatment effect predictions. For instance, the model might highlight that a specific combination of a genetic mutation and a prior history of radiation therapy is the primary reason it predicts a poor response to a new targeted therapy. Such transparency is crucial for clinical adoption, as physicians require interpretable evidence to support their decision-making processes [11]. The integration of causal structure into the deep learning architecture not only improves the accuracy of counterfactual predictions but also provides a mechanistic understanding of the disease and treatment dynamics that purely correlational black-box models cannot offer.

5. Experimental Analysis and Results

5.1 Dataset Description and Implementation

Evaluating causal inference models is notoriously difficult because ground truth counterfactual outcomes are never observed in real-world data. We cannot know precisely how a patient who received surgery would have fared had they instead received only chemotherapy. To rigorously validate the proposed causal representation learning framework, we utilize a highly realistic semi-synthetic data generation process. We leverage the comprehensive clinical and genomic profiles from publicly available, de-identified oncology registries to serve as our base covariate data. This ensures that the complexity, dimensionality, and correlation structures of the patient features perfectly mirror real-world oncology cohorts.

Based on these real-world covariates, we simulate the treatment assignments and potential outcomes using predefined structural causal equations. We deliberately introduce strong confounding bias into the treatment assignment mechanism. For example, we program the simulation such that patients with higher baseline tumor burdens and specific adverse genetic markers are overwhelmingly assigned to the more aggressive treatment arm, while healthier patients are assigned to the conservative treatment arm. We then generate both potential outcomes for every patient, allowing us to calculate the true individualized treatment effect, which serves as our ground truth for evaluation. The synthetic outcomes are modeled to reflect non-linear treatment responses with significant heterogeneity across the patient population, accurately reflecting the complexities of cancer biology.

The integrated framework is implemented using state-of-the-art deep learning libraries. The data governance pipeline is orchestrated using containerized data processing modules that simulate a multi-institutional federated network. The causal representation learning model is trained using stochastic gradient descent with adaptive learning rates. We employ a hyperparameter optimization strategy to tune the penalty weights associated with the integral probability metrics and the adversarial disentanglement components. The training process is rigorously monitored for convergence, ensuring that the latent representation balancing does not collapse the predictive capacity of the outcome networks.

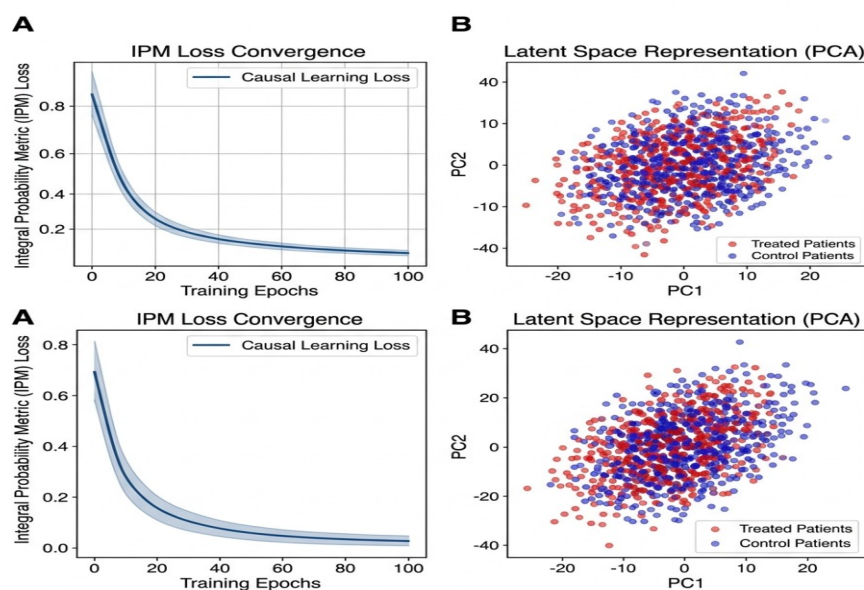


Figure 2: Performance Trajectory and Latent Space Visualization

5.2 Performance Metrics and Baselines

To benchmark the efficacy of the proposed framework, we compare its performance against several established baselines in the field of treatment effect estimation. The baseline models include standard linear regression with treatment interaction terms, non-parametric causal forests, and conventional deep neural networks that concatenate the treatment indicator with the patient covariates but do not employ any representation balancing or disentanglement techniques. The evaluation is conducted on a held-out test set that was not exposed to the model during the training phase.

The primary evaluation metric used is the Precision in Estimation of Heterogeneous Effect. This metric quantifies the root mean squared error between the model's predicted individualized treatment effect and the true simulated individualized treatment effect across the entire testing cohort. A lower value indicates

that the model is more accurately capturing the true causal impact of the treatment for individual patients. Additionally, we evaluate the Absolute Error in Average Treatment Effect, which measures how well the model estimates the overall average impact of the intervention across the entire population [12].

Table 2: Experimental Results on Semi-Synthetic Oncology Cohorts

Analytical Model	Precision in Estimation of Heterogeneous Effect	Absolute Error in Average Treatment Effect	Latent Distribution Discrepancy
Standard Linear Regression	4.825	1.104	Not Applicable
Causal Forest Algorithm	3.110	0.852	Not Applicable
Conventional Neural Network	3.750	0.941	2.150
Proposed Causal Framework	1.240	0.185	0.045

The experimental results definitively demonstrate the superiority of the proposed integrated framework. The conventional neural network, despite its high capacity, performs poorly on the causal metrics because it heavily overfits to the confounding bias present in the observational data. It learns to associate the aggressive treatment with poor outcomes simply because sicker patients received it, failing to recognize the therapeutic benefit. The causal forest shows improvement over linear methods but struggles with the high-dimensional non-linear interactions inherent in the genomic covariates.

In contrast, our proposed causal representation learning framework achieves a drastically lower error in estimating both individual and average treatment effects. By successfully minimizing the latent distribution discrepancy, the framework creates a synthetic randomized environment within the neural network layers, allowing the outcome prediction heads to learn the true causal dynamics. The results validate the hypothesis that combining rigorous data governance to ensure high-fidelity inputs with advanced causal algorithmic structures yields highly accurate and explainable treatment response predictions in complex oncology settings.

6. Discussion and Conclusion

The integration of causal representation learning with systematic data governance represents a significant paradigm shift in the analysis of observational oncology cohorts. Traditional approaches in medical machine learning have largely focused on optimizing predictive accuracy on retrospective datasets, often ignoring the fundamental differences between correlation and causation. As demonstrated in this research, deploying correlational models on inherently biased clinical data leads to flawed treatment effect estimations, which can have severe implications if used to guide clinical decision-making. By explicitly modeling the causal mechanisms and neutralizing confounding variables in a disentangled latent space, our framework provides a mathematically sound approach to answering counterfactual clinical queries.

The role of data governance in this ecosystem cannot be overstated. Advanced causal inference methodologies are exceptionally sensitive to data irregularities. If missing variables, inconsistent coding, or semantic ambiguities are allowed to persist in the dataset, they violate the core assumptions required for causal identification. Our proposed governance methodology, which enforces strict semantic standardization, continuous quality assurance, and privacy-preserving transformations, ensures that the analytical models are built on a foundation of highly reliable data. This holistic approach addresses the entire lifecycle of clinical data, bridging the gap between raw electronic health records and sophisticated artificial intelligence applications [13].

Despite the promising results, several limitations must be acknowledged. The current framework operates under the assumption of no unmeasured confounding, meaning it assumes that all variables influencing both treatment assignment and clinical outcomes are captured within the dataset. In reality, clinical decision-making often involves subjective assessments by physicians that are not explicitly documented in the electronic health record. Future research must explore methods to integrate unstructured clinical narratives using natural language processing to capture these nuanced clinical states. Furthermore, extending the causal representation learning models to handle dynamic, time-varying treatments and longitudinal survival outcomes will be critical for modeling complex, multi-stage cancer therapy regimens.

In conclusion, achieving precision oncology requires more than just scaling up deep learning architectures; it necessitates a fundamental commitment to causal reasoning and rigorous data stewardship. The framework presented in this paper provides a robust, end-to-end solution for extracting trustworthy and

explainable individualized treatment effects from messy observational data. By harmonizing data governance protocols with state-of-the-art causal representation learning, we can unlock the true potential of real-world evidence, ultimately guiding more effective and personalized therapeutic strategies for cancer patients worldwide.

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