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Chapter 7: Generative Models for Clinical Data Augmentation

7.1. Introduction

Generative models can assist in augmenting clinical datasets to address the data scarcity that limits the application of complex predictive models. The opportunity remains to evaluate how generative models can be applied to the augmentation of clinical datasets while satisfying a number of requirements. First, the generative model should be suitable for modeling high-dimensional tabular data with missingness, as all clinical data have the tabular representation of the schema of medical record. Second, the model should support proven techniques for dealing with imbalanced class distributions, since the clinical task usually appears as predictive modeling with imbalanced class distribution. Finally, prior to the use of augmented data for predictive modeling, it needs to demonstrate that augmentation of training samples using generative models can improve model fairness-aware fairness with respect to sensitive attributes.

Generative models have the potential to augment clinical data efficiently in that suitably modeled generative models can capture the underlying multinomial and conditional distributions and can be used to sample more data. Properly done, augmentation with generative models can also help address class imbalance — a common problem in clinical datasets — without incurring the drawbacks of resampling techniques. Nevertheless, clinical data augmentation using generative models should be treated with care as it could fail to provide improvements or even degrade outcomes when sufficient quality real-world data are available. Maintaining model calibration while obtaining diverse samples from the generating distribution is key to ensuring the reliability of augmented data.

7.2. Background

Augmenting clinical data is becoming increasingly relevant for several reasons. First, large real-life datasets are often unable to cover all rare events reliably due to their low count in the population. Second, training predictive models with fewer examples of certain classes may lead to biased predictions when the model is deployed, e.g., for classifying diseases. Third, these data may sometimes be too sensitive to share, limiting model training. Fourth, models trained on predictive tasks may not generalize well to unseen data due to a lack of knowledge about the data distribution. Finally, models candidly tested in real-life clinical settings may face legal issues should the experimental group perform poorly compared to the control. Thankfully, the growing field of generative models attempts to tackle these augmentation needs.

While data augmentation has a long history in computer vision, its application within healthcare is growing. Traditionally, augmentation techniques have been handcrafted and domain-specific, usually addressing data scarcity, preventing overfitting, improving model robustness, circumventing privacy issues with synthetic data, or carefully reshuffling variables before using models trained on the permuted data. More recently, GANs were suggested to conditionally model tabular data. Such models now range from GANs to VAEs, diffusion, and diffusion-like methods capable of addressing other aspects of augmentation for clinical data.

Clinical datasets may also exhibit other complex characteristics. For instance, the data distribution may not be the product of independent sources (e.g., age tends to correlate with heart diseases), the missingness may occur as a result of non-ignorable or informative mechanisms, and the data itself may carry potential biases or confounding effects. Consequently, the analysis is permeated with fragmentation, imbalance, and high-dimensionality issues. Addressing them requires a careful choice of data sources along with the models used and their combinations, with additional attention paid to the training and evaluation of the prediction models post-augmentation.

7.2.1. Clinical Data Characteristics

The variety of clinical data is vast, and its precise characteristics should be acknowledged before determining the appropriate method and model. Clinical Data Augmentation relies on Generative Models, yet recent notable works still tend to ignore that clinical data is tabular. Furthermore, tabular data in healthcare is particularly prone to distribution shifts, has inherent biases and ethical considerations, and often contains imbalanced classes and rare events. Prior to addressing how these characteristics might affect the choice of generative model, these facets should be reviewed in greater detail.

Clinical datasets are typically composed of tabular data. However, tabular data may be longitudinal, like Electronic Health Records, or not. In addition, there might be time-series data for a subset of patients or even only for a single patient. The data might also come from a single hospital, several hospitals, or even several countries. Front-line healthcare workers deal with an overwhelming amount of data. Nevertheless, a large part of it is not used in predictive models. Predictive modeling with tabular data is also limited, particularly for rare-pathologies. Risk stratifications applied to those pathologies might suffer from overfitting. Augmentation of the dataset is thus a valid approach, especially for augmentation of minority labels. The Generative Model used should be chosen according to the particular setting.

7.2.2. Data Augmentation in Healthcare

Research has shown that the aforementioned issues translate into severe challenges when training supervised predictive models. The scarcity of labelled data is not always the only issue, however: in some scenarios, the data is available but practical deployment is hampered by the high cost of (i) data collection, e.g. adverse events estimation in road safety prediction scenarios, (ii) time, e.g. rare but life-threatening diseases such as sarcomas, or (iii) in both aspects, e.g. the implementation of generative models for data augmentation in mental health. Being such a safety-critical domain, predictive models in healthcare also require generalisation across regions of significantly different population, sign, symptoms, or even genetic predispositions. Even when labelled data is readily available and the region shift is small, models might suffer from privacy-related issues, with for instance image-based models unable to satisfy the privacy risks imposed by HIPAA when trained on actual dataset.

Classically, along with the previous two reasons, the data augmentation methods followed a rule-based scripted approach, creating new labelled observations based on transforms, selection and modification of certain areas or values in the available observations. These classical rule-based methods have now been broadening to data generation through generative modelling, where the latter leverages unsupervised or self-supervised embeddings from the existing information to produce new labelled observations. The expansion of possible synthetization techniques, as well as the always accurate synthesis-consistency requisition to avoid unexpected occurrences in the augmented dataset have allowed also the application of data augmentation to other information represented in different formats or in disparate domains like genomic or odontal data.

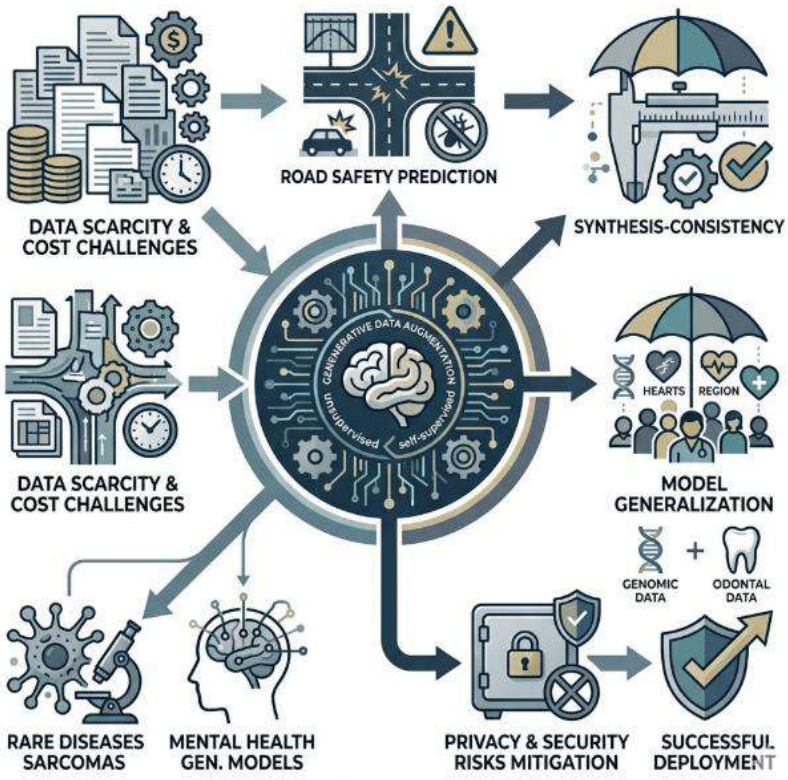

Fig 7.1: A Generalization and Privacy-Preserving Framework for Generative Data Augmentation in Safety-Critical Domains: Leveraging Self-Supervised Embeddings across Healthcare and Road Safety Applications

7.3. Data Preparation and Privacy Considerations

Data preparation and privacy-related considerations constitute the initial phases of applying generative models to clinical data augmentation. Fulfilling data governance requirements ensures that the information can be usefully employed, including in generative models that may complete missing values. De-identification safeguards patients' identities and evaluations of the residual risk guarantee a sufficient level of protection.

Data governance in health-care settings is subject to stringent rules. Key aspects involve clarifying data purpose and recipient. When using patient records for external research, a Data Transfer Agreement must be signed, confirming that the data recipient cannot link information to the patient identity and will not use it for other purposes. Prior to agreement signature, the request for external use must pass ethics committee approval.

Patient records for Machine Learning applications are conventionally de-identified, stripping away or encoding explicit identifiers (e.g., name, Social Security number). However, even when identifiers are removed, other details could allow reconstructing patients' identities. Therefore, the de-identification process must reduce the risk of a privacy breach to a level deemed acceptable in relation to the data purpose. Evaluating the risk of re-identification considers properties of the clinical data (e.g., number of patients, number of variables, redundancy) and available external information (e.g., population distribution, alternative datasets). Recent findings emphasize the utility of clinical records for identity reconstruction, especially in the case of non-acute diseases that imply stable medical and geographical conditions. As a result, Hyland et al. propose a three-step de-identification approach based on K-anonymity, L-diversity, and T-closeness.

In addition to these generic rules, local requirements and initiatives may impose stricter regulations. The Italian Ministry of Health proposed the Heracles guidelines for health-care institutions involved in clinical trials. Also, the regulations of the Country Code of the Italian National Health Service envisage that participating patients can approve the use of their data for subsequent research only if they have been informed of how the data will be managed, including de-identification.

7.4. Methodological Frameworks

Building upon a previously established academic foundation, a suite of Generative modeling approaches has been developed for Tabular Clinical Data augmentation. These Generative techniques provide a means to increase the size of Clinical Data sets via data-driven, domain-knowledge aligned Synthetic Data generation. The utilization of these models is designed using step-by-step Psychedelic guidelines, spanning End-to-End & Downstream Impact Evaluation of Synthetic Augmented Data in Clinical Predictive Modelling.

Generative model types that are suitable for Tabular Clinical Data augmentation comprise GANs, VAEs, Diffusion and Diffusion-like methods. For a Markov Random Field-based Conditional Data-Driven (CDP-CGGAN) Scheme based on a Novelly defined LGTD Image-Prior distribution the Experimental results demonstrate enhanced performances in multiple criteria axes. Techniques to alleviate issues pertaining to Class Imbalance, Rare event prediction and Subgroup augmentation are discussed, including Resampling, SMOTE and SMOTE-variants for Generative resampling. Caveats surrounding Data-Quality concerns, Big Data representations, Synthetic Minority Over-Sampling Technique utilisation, Class Ratio Modelling, Presence of additional noise and Explaining Models on Data synthesized using SMOTE variants are also briefly reviewed.

7.4.1. Model Selection for Tabular Clinical Data

The growing use of generative deep learning in many domains has elicited parallels in healthcare. A number of studies have proposed GANs, VAEs, or Diffusion models for augmenting clinical data. All these models tackle tabular data. However, different generative models and, in particular, training paradigms produce different outcomes. Selecting the appropriate model depends on the dataset and the analytical goals. Seven properties are introduced and used to assess model suitability for tabular clinical datasets: support of categorical variables, provision of latent space, ease of conditioning, ability to administer patient groups, supervision capabilities, and integration of domain knowledge and template information.

Class imbalance and data scarcity pose challenges to predictive models in many domains, including healthcare. Tabular clinical data are notoriously imbalanced; models based on the minority class can lead to poor overall predictions. Simple oversampling is often insufficient to address issues of bias and uncertainty in highly imbalanced classes. An ad hoc probabilistic formulation enables secondary generation of rare events or classes in a trans-dimensional manner conditional on class. Synthesis does not entail retraining the entire generative model but exploits class probability from a pretrained conditional GAN, with synthetic samples drawn from a transfer matrix for imbalanced minority classes.

7.4.2. Handling Imbalanced and Rare Events

Because healthcare datasets are commonly biased and contain rare events, generative augmentation should address these challenges independently. The distribution of clinical events is generally unbalanced, leading to few samples associated with specific conditions. In addition, most hospitalizations and deaths result from rare combinations of diseases or symptoms. Standard classifiers are usually optimized for the majority classes, but augmenting the decision boundary should improve performance on underrepresented conditions.

The simplest way to address class imbalance is to oversample the minority classes. Nevertheless, this is not always the most suitable approach, especially when the model is applied to rare events. Generative Adversarial Networks can be deployed to increase the risk of infrequent diseases or indicate rare responses to dictatorial treatments. The Synthetic Minority Over-sampling Technique and extensions, such as SMOTE-Boost, also work well. These approaches synthesize new samples for the classes that contain few observations. However, caution is warranted; oversampling alone does not guarantee predictive gain and can exacerbate overfitting. Therefore, validation on an independent test set with a representative class distribution is indispensable.

The risk of rare events is mostly an optimization problem with limited availability of positive samples. For instance, hospitals may report several post-surgery deaths but rarely have cases of clotting disorders after specific types of surgery. Because these events are infrequent and clinical data are often unbalanced, risk prediction models tend to favour negative predictions and suffer from low sensitivity. Rather than simply oversampling minority classes, a straightforward solution lies in increasing synthetic reports of these conditions. This can be achieved by modeling the underlying risk of the clinical model.

7.5. Evaluation Strategies

Establishing the validity and usefulness of generated samples is essential and can be approached from different angles. Initially, statistical metrics help ensure the output distribution of the generative model is aligned with that of the original training data distribution. Fidelity and diversity are then used to measure the quality of generated samples independently of any downstream tasks. Subsequently, testing whether the synthetic samples enable better-performing classifiers is crucial, as improving predictive model performance is often the primary objective. Other desirable characteristics in this context include fairness and robustness, particularly against adversarial attacks, and evidence supporting a direct contribution to the generative process should also be provided.

Various types of statistical metrics can help ascertain whether the output distribution is desirable. Fidelity measures the extent to which the surrogate distribution approximates the real data distribution, usually evaluated with kernel density estimation or Kullback-Leibler divergence. Diversity, on the other hand, quantifies the extent of mode collapse, for example, using total variance distance or Jensen-Shannon divergence. A third important aspect is privacy risk, which can be assessed through the risk of adversarial re-identification evaluated with a membership inference attack. Lastly, calibration is relevant when class-conditional distributions are generated.

7.5.1. Statistical and Clinical Validity

Establishing the validity and utility of generated samples is vital. Statistical metrics can capture sample fidelity (similarity to real data), diversity (range of generated samples), privacy risk (likelihood of identification), and calibration (alignment between data and labels). Fidelity during training is tracked through conditional distributions and should extend to targets, especially for classification tasks. Statistical tests are recommended to ensure sufficient diversity. Privacy-preserving masks (e.g., K-anonymity) can help

control the risk of re-identification, although quantifying the level of individual risk remains challenging.

Clinical validity hinges on domain experts (e.g., clinicians, epidemiologists, biostatisticians) who evaluate whether the samples would be clinically useful within a predictive modeling framework. Assessing downstream impact on predictive models is another strategy, where the effect of augmentation on performance, fairness, and robustness is monitored. Use of only a small proportion or a small number of generated samples during training is prudent for initial evaluations.

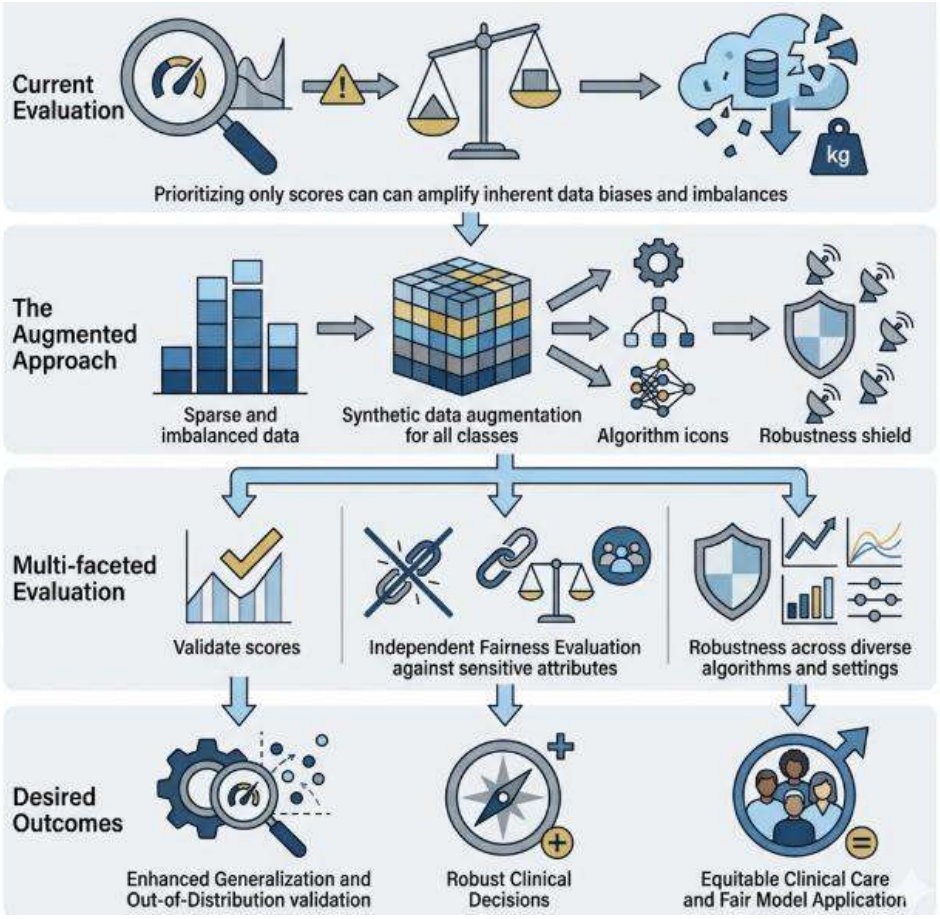

Fig 7.2: Evaluating Data-Augmentation Pipelines for Fairness, Robustness, and Generalizability in Clinical Predictive Modeling

7.5.2. Downstream Impact on Predictive Modeling

The impact on predictive performance constitutes a commonly adopted and informative evaluation strategy. However, it requires care because an augmentation pipeline that focuses primarily on enhancing predictive scores in a downstream task might inadvertently incorporate biases, especially when the underlying clinical data sources are imbalanced. The degree of augmented class imbalance can be overlooked, and classifiers such as random forests can exploit augmentations to compensate for lack of informative features. Therefore, apart from validating scores on the sensitive downstream task, it is also recommended to independently evaluate fairness against the targeted sensitive attributes and to explore the robustness of these properties across several supervised algorithms and their hyperparameter settings.

To achieve robust predictions, a minimal data-augmentation pipeline must generate a sufficient number of synthetic samples for all the clinically relevant classes. Data-augmentation techniques often amplify the models' ability to generalise by providing informative samples in data-scarce areas of sensitive attributes and by proactively enabling out-of-distribution validation. Any clinical-decision predictive model can benefit from augmentation as long as these considerations are respected.

7.6. Applications and Case Studies

The potential of generative models to augment clinical data is illustrated by two applications. The first investigates the role of augmentation in workflows based on Electronic Health Records (EHRs). The second considers genomic and -omics data, where the existing patient cohort is limited relative to the data dimensionality. In both cases, augmentation using generative methods is shown to maintain consistency with the underlying clinical schemas.

The first example assesses the impact of augmentation with synthetic clinical histories on predictions of mortality within three months following a hospital admission. The EHRs consist of tabular longitudinal sequences with temporally structured categorical, ordinal, and real-valued variables. Patient trajectories are organized according to the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) data standard, providing a common schema for healthcare data exchange. Synthetic data generation is addressed from a supervision-centered viewpoint, with attention to two major requirements: consistency with the schema and improved predictive performance through augmented class balancing. Clinical validation is conveyed by measuring calibration during predictive modeling with the credibility curves proposed for quantifying the calibration of deep networks.

7.6.1. Electronic Health Records

It is essential to assure that synthesized samples preserve both clinical plausibility and logical coherence with respect to the data schema adopted in the EHR main workflow. Data augmentation in Electronic Health Record (EHR) data is a two-step process: first, a model is trained to create a sufficiently large set of synthetic data points, afterwards those synthetic patients are incorporated in the real data by further synthesis or replacement of the original values. Conditionally synthesizing EHR data while adhering to the columns of the original tables without getting lost in cryptic corner cases is still an open problem. However, many real use-cases in the medical domain can be addressed, including radiological reports, chest X-rays and more. The extension of Realistic Patient Generator (RPG) with these augmentations makes it a fully working tool to do quality and quantity augmentation of clinical patients in a EHR environment.

7.6.2. Genomic and -Omics Data

In addition to utilizing Electronic Health Records, augmentation is also beneficial when modeling -omic and -omic-like data drawn from small-sized cohorts. These -omic datasets are often high-dimensional, heterogeneous, with clinical labels that may be rare or even absent for some patient subgroups. Progressive Knowledge-based Mutation (PKM)-based pathway mutation profile-derived -omics multi-component assays, collected from patients with uterine corpus endometrial carcinoma in The Cancer Genome Atlas (TCGA), were chosen to illustrate the augmentation, to robustly study disease for clinical prediction and translational medicine applications. Distinct -omics multi-component assays were first characterized among the patients based on the clinical labels. Then, in order to facilitate better understanding of disease for future clinical application, augmentation was conducted based on the data characteristics within all the distinct -omics multi-component assays.

Nevertheless, since the sizes of these component datasets are still relatively small, PKM-based pathway mutation profile-derived methylation can be leveraged to further facilitate better understanding of subtype-specific disease within -omic multi-component diseased datasets. However, proper segregation of the pathway mutation profile-derived methylation across the two types of endometrial carcinoma is critical. At the same time, rare mutation profile-derived methylation alterations should also be emphasized, since these are crucial to harm and mislead the patients with histological type 1 endometrial carcinoma. Based on above considerations, augmentation of TCGA cohort samples within the above -omic multi-component datasets, including eRNA and pathway mutation profile-derived methylation, is strongly desired.

7.7. Ethical, Legal, and Social Implications

The capability of generative models to synthesize new and diverse data has opened avenues for a widening range of applications and potential uses. In addition to privacy preserving data sharing, carefully crafted generative models can help addressing the scarcity of clinical data in some applications. By exploring previously unseen data distributions, synthetic data also poses the opportunity to debias predictive models and check for performance in underrepresented domains. While these applications are closely related to the ability of the model to learn the underlying data distribution, they may not require a high-quality approximation of the data density function, which is likely a much more difficult task. Nevertheless, the novelty, accessibility, and growing number of applications based on synthetic data raise important ethical, legal, and social implications regardless of quality. Key concerns include the use of synthetic data without proper consent, lack of clarity and transparency about its true origin, as well as the potential for model bias, discrimination, and society-wide impact. Synthetic data can also pose a risk to patients' privacy, especially when susceptible to membership inference attacks.

The use of synthetic data in any application must be driven by a responsible approach to data governance. For instance, organizations might consider developing a governance framework at a hierarchical level comprising the entire organization. In addition, the importance of responsible and secure data sharing must be considered. Unlike traditional datasets, the careful deployment of generative models for synthetic data generation alleviates the need to transfer sensitive data between entities. Synthesizing data where it is stored creates the opportunity to combine information held securely in silos owned by different organizations by sharing only the synthetic data, which ultimately represents a carefully crafted alternative. Because only the model parameters, and not the actual hosting data, are shared, such an approach may enhance data security and response to institutional and regulatory requirements.

7.7.1. Ethical Considerations and Societal Impact

The incorporation of synthetic clinical data raises ethical and regulatory concerns that remain inadequately addressed in the scientific literature. Public sharing and distribution of synthetic data products is complex due to issues of consent, ownership, privacy, and distribution policy for clinical data; these issues are further compounded by the fact that currently available methods do not allow for guarantees of the absence of perturbations of the original data in the synthetic data. Promotion of the idea that synthetic data is free from the privacy concerns posed by real clinical data can also increase the risk that clinical information can be compromised by re-identification.

In addition, special attention must be given to the presence of biases and the limitations of synthetic clinical data. Despite its importance for several predictive modeling problems within clinical data science and medicine, the societal implications of synthetic clinical data remain largely unexplored. Generative models capable of augmenting clinical data can mitigate the problem of data scarcity without compromising the privacy of the patients, but it is fundamental to guarantee that the problem of augmentation does not mask the original clinical data within the synthetic data. Moreover, synthetic data should lose the risk of data breaches that represent a real concern in the clinical field. Therefore, it is needed to consider additional ramifications to understand the opportunity of these methodologies within the clinical environment.

7.8. Challenges and Limitations

Current works-in-progress perform evaluations based on consistency checks and task-specific predictive modeling. The development of quality assessment criteria tailored to data augmentation is necessary, as traditional measures of generative modeling have limited correlation with augmentation effectiveness. Current use cases are limited to tabular data types, while longitudinal relationships, common in electronic health records, remain unexplored. Theoretical and practical foundations must be established. Task decomposition may mitigate domain discrepancies between real and synthetic data; however, the clinical realism of individual components requires validation.

Tabular data quality remains a major concern. Scattered distributions and imbalanced classes, particularly for rare events, challenge model fidelity. Once quality deficits are addressed, adequate supervision becomes paramount. Supervised classifiers are typically superior to unsupervised counterparts; however, viable labeled samples are usually scarce. Augmentation may alleviate this issue by facilitating resampling or Synthetic Minority Over-sampling Technique-like approaches, but caution is advised. Direct evaluation of augmentation impact on supervised task performance is typically more relevant than evaluation of augmentation quality itself.

7.8.1. Obstacles and Constraints in Data Utilization

To successfully apply augmented clinical data, several obstacles need to be overcome. First, achieving sufficiently high-quality synthetic data is essential, since machine learning models may memorize weaknesses instead of generalizing to real data. In particular, existing models still struggle with high-dimensional, heterogeneous, longitudinal, or sparse data. Second, generating large amounts of clinical data is difficult without augmenting at least one modality—generative adversarial networks (GANs) and similar models often cannot be directly applied for supervised learning tasks with highly

imbalanced datasets. Third, domain shifts introduced during augmentation may give rise to performance drops for models trained with augmented datasets. Fourth, no standard evaluation criteria exist for the validity of generated clinical data, making reproduction and comparison across studies difficult. Finally, generated samples need to be accepted by regulatory agencies, such as the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), before being used to support product submissions for new drugs or medical devices.

Synthetically generated clinical data can pose ethical and legal challenges as well, particularly from the perspective of the healthcare system. Synthetic data can replicate the original data distribution, but data owners, including hospitals, might expect that their information remains private as a consequence of existing privacy policies such as Health Insurance Portability and Accountability Act (HIPAA) or General Data Protection Regulation (GDPR). Hence, data owners have not been offered compensation for participating in the synthetic data generation process, and thus do not see the same benefits as the organizations which have taken advantage of it. Rather than fully de-identifying data samples when sharing clinical information with researchers, future frameworks should consider sharing the data in a governance way with clear processes and adequate tools to allow data owners to evaluate the trustworthiness of the augmentations being produced.

7.9. Future Directions

Research priorities should address several issues in generative clinical data augmentation. First, although augmentation aims to compensate for low-quality data and hence to mitigate learned biases, directly evaluating these hypotheses remains elusive. Second, approaches using generative models degrade when applied to low-quality data, making the quality of the underlying dataset critical. Third, despite evidence that augmentation can help bridge domain shifts, most strategies do not consider the potential effect of a domain shift between training and inference. Fourth, although automatic evaluation metrics can assist developers of generative models, they should not preclude validation using application-specific downstream tasks. Fifth, generative augmentation has proven beneficial for predictive task performance, improving classification and regression results on both global and subgroup levels; however, the assessments are limited and require independent verification using other tasks and source/target dataset pairs. Sixth, only a handful of recent studies have evaluated the potential for augmentation to improve equity in clinical prediction or recommendation tasks, despite the obvious ethical importance of the question. Finally, the use of synthetic data in healthcare raises various legal, ethical, and societal concerns that have yet to be

addressed in sufficient depth. Collectively, these issues highlight critical areas of focus for researchers interested in generative augmentation of clinical data.

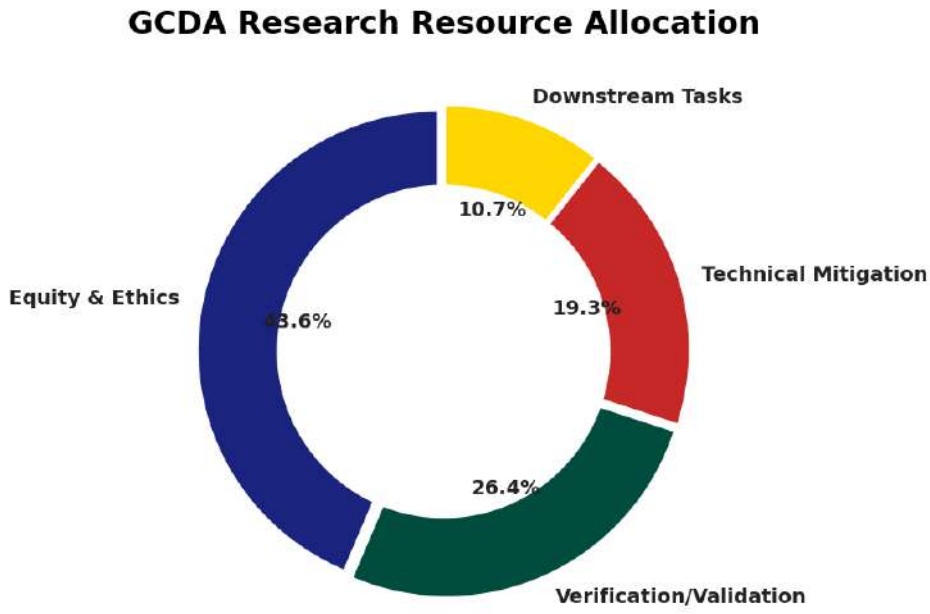

Fig 7.3: GCDA Research Resource Allocation

7.10. Conclusion

The presented research explored generative models as tools to augment clinical datasets. Such models learn data distributions from existing data to synthesize new instances that imitate the original population in terms of statistical properties. Despite being an established approach in various domains — notably computer vision and natural language processing — generative models have yet to gain traction within healthcare, where the potential utility is hindered by both data scarcity and extensive privacy constraints. While existing works have begun applying such models to Electronic Health Records (EHR) data, research remains fragmented, lacking comprehensive best practices.

The research provided a thorough synthesis of the key aspects of applying generative models in healthcare on tabular clinical data. Starting with a clear understanding of the data used in healthcare, particularly EHRs, it was possible to articulate the rationale for stimulation in this domain. Subsequent sections examined the methodological and evaluative aspects, detailing data preparation, how privacy regulations affect the use of generative models, and model selection while bridging with the known issues of imbalance prevalent in clinical datasets. In essence, the research constituted an initial

roadmap to deploying generative models with tabular clinical data, offering guidance for testing in downstream predictive modeling tasks. Further developments hold the promise of establishing yet another approach in the healthcare domain for training data-hungry machine learning algorithms, ultimately aiming at an augmentation strategy similar to computer vision.

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