Generative Artificial Intelligence for Synthetic Medical Data Generation with Privacy Preservation and Clinical Utility Assessment

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Abstract

Synthetic medical data offer a pathway to develop and evaluate predictive systems while reducing routine access to identifiable patient records. This paper proposes a governed generative artificial intelligence framework combining conditional tabular synthesis, privacy accounting, disclosure-risk testing, distributional fidelity, and downstream clinical utility evaluation. The architecture separates controlled data preparation, model training, synthetic release, and independent auditing. It specifies conditional diffusion and adversarial baselines, differential privacy options, clinical constraint checks, membership-inference testing, subgroup evaluation, and release decisions under explicit thresholds. An illustrative numerical scenario demonstrates how model choice and privacy budgets can trade off fidelity, predictive utility, and attack resistance; these figures are constructed examples, not observations from patients or completed experiments. The study contributes an auditable evaluation protocol and reproducibility plan for future empirical validation. It concludes that synthetic data should be treated as a risk-managed research artifact rather than inherently anonymous clinical information.

Keywords: Generative artificial intelligence; synthetic health records; differential privacy; clinical utility; disclosure risk; conditional diffusion; fairness; data governance.

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1. Introduction

Modern healthcare produces longitudinal electronic health records, laboratory observations, diagnoses, medication histories, physiologic streams, and imaging reports. These resources can support predictive analytics and public health research, but access is constrained by confidentiality obligations, fragmented governance, institutional silos, and the potential for reidentification. Conventional deidentification removes direct identifiers but may leave distinctive combinations of dates, rare conditions, and treatment trajectories. A data-sharing strategy therefore requires more than deletion of names: it must consider how statistical information about individuals can be inferred from the released material.

Generative artificial intelligence has emerged as a possible complement to controlled access. A generator learns patterns in an approved training cohort and produces new records that resemble the source distribution without intentionally copying individual records. The approach can accelerate software testing,

education, feasibility studies, algorithm prototyping, and cross-institutional collaboration. However, resemblance alone is not evidence of privacy. Overfit models may memorize unusual patients, and a plausible synthetic record may violate clinical logic or misrepresent disease prevalence.

Synthetic data quality has several distinct meanings. Statistical fidelity concerns whether marginal distributions, correlations, and temporal patterns resemble the original cohort. Clinical plausibility concerns whether the records obey physiologic ranges, medication contraindications, diagnostic dependencies, and longitudinal ordering. Predictive utility asks whether models trained on synthetic examples transfer to an untouched real-world test population. Privacy asks whether the release increases an adversary's ability to infer membership, attributes, or the presence of rare patient trajectories.

These objectives conflict. A generator that reproduces very fine-grained associations may support useful clinical modeling but also expose uncommon records. Stronger noise and restricted conditioning can lower disclosure risk while damaging minority subgroup fidelity. Evaluating only overall accuracy or a single similarity score obscures such tradeoffs. This paper consequently frames synthesis as a constrained multiobjective problem, rather than maximizing visual or numerical resemblance alone.

Healthcare datasets also differ from ordinary benchmark tables. Missingness can encode care processes; laboratory units vary across institutions; treatment is confounded by clinical severity; outcomes can be censored; and encounter sequences are irregular. A credible generator must preserve the distinction between a missing value and a true zero, represent categorical hierarchies, and avoid inventing impossible causal orderings. Synthetic observations should never be assumed to validate clinical effectiveness merely because they look realistic.

The proposed framework is intended for structured, patient-level medical data, including a possible longitudinal extension. Its primary model is a conditional diffusion generator for mixed data, with a conditional adversarial generator as comparator. Data are partitioned at the patient level before preprocessing to prevent leakage. Training can incorporate differentially private optimization, and the release gate uses multiple independent attack and utility checks. The procedure is designed so that institutional teams can substitute real datasets and execute the specified analyses.

The central research questions are whether generated records preserve clinically relevant structure, whether privacy controls measurably reduce exposure to inference attacks, whether synthetic training data yield transferable risk prediction, and whether subgroup performance remains acceptable. Rather than asserting unverified experimental superiority, the paper defines testable hypotheses, decision thresholds, and an illustrative worked example. This distinction is particularly important because fabricated performance claims could distort medical AI development.

The manuscript makes three contributions. First, it integrates preprocessing, conditional generation, privacy budgeting, and governance into a single traceable pipeline. Second, it defines a layered assessment combining distributional tests, train-on-synthetic-test-on-real validation, clinical-rule compliance, membership inference, and subgroup error analysis. Third, it presents a transparent hypothetical results template that shows exactly how a future experiment could report model comparisons without confusing demonstration figures with evidence.

Practical adoption requires human review. Clinical experts should inspect high-risk variables and relationships, privacy officers should approve release conditions, and independent analysts should attempt to attack the output. Model cards, provenance logs, random seeds, cohort definitions, and data-use

restrictions support reproducibility. If the synthetic cohort fails any mandatory gate, the proper response is to revise the generator or withhold release rather than to average away a critical failure.

Ultimately, the promise of generative medical data is not that it eliminates the need for secure access to real information. Its value is to reduce unnecessary exposure while preserving enough structure for carefully scoped analytical tasks. The framework therefore emphasizes proportionality: different downstream uses justify different utility requirements and privacy thresholds. Clinical deployment, especially patient-level decisions, requires separate prospective validation on real populations.

2. Literature Review

Early synthetic health data work drew on probabilistic graphical models, parametric sampling, and rule-based simulators. These approaches can offer interpretable assumptions and straightforward control of selected marginal distributions, but they often struggle with nonlinear dependencies and heterogeneous data types. Their transparency nevertheless makes them useful baselines: complex generators should demonstrate measurable improvement over simpler alternatives rather than rely on architectural novelty.

Generative adversarial networks introduced an adversarial learning mechanism in which a generator competes with a discriminator [1]. In tabular healthcare applications, conditional GAN variants such as CTGAN address imbalanced categorical values and mixed numerical distributions [2]. Adversarial training can reproduce useful correlations but may be unstable under rare-class imbalance, and a discriminator score is not a complete clinical validation measure.

Variational autoencoders learn a latent distribution through a reconstruction and regularization objective [3]. They can provide relatively stable optimization and smooth sampling, yet oversmoothing may diminish rare-event signals that matter for clinical risk stratification. Comparisons among GANs, VAEs, and diffusion models must therefore examine clinically meaningful endpoints, not only global resemblance.

Denoising diffusion probabilistic models learn to reverse a sequence of noise perturbations [4]. Their iterative generation process has inspired tabular adaptations and offers flexible conditional sampling. Mixed-type health records require special handling of discrete codes, bounded laboratory measurements, and structural missingness. Diffusion models are promising but are not inherently private: training objectives and output filters must still be evaluated for memorization.

Privacy research distinguishes removal of explicit identifiers from formal protection. Differential privacy bounds how much the output distribution can change when one person is added or removed [5]. Differentially private stochastic gradient descent uses clipped per-example gradients and calibrated noise [6]. The resulting privacy budget depends on sampling, training iterations, noise scale, and accounting assumptions; a reported epsilon is meaningful only with its delta, neighboring-dataset definition, and accountant.

Membership inference attacks attempt to determine whether a record participated in model training [7]. Attribute inference and nearest-neighbor analyses probe related but distinct threats. A low attack score under one adversary does not establish universal anonymity, particularly when attackers possess external registries or knowledge of rare diagnoses. Strong evaluations should report attack baselines, confidence intervals, and realistic threat models.

The synthetic-data literature also distinguishes resemblance from utility. The train-on-synthetic-test-on-real protocol evaluates whether synthetic records support learning that transfers to a held-out real cohort. Conversely, train-on-real-test-on-synthetic can reveal coverage limitations but is insufficient by itself. Evaluation should include calibration, discrimination, sensitivity at operating thresholds, and subgroup robustness rather than overall classification accuracy alone.

Healthcare data have causal and institutional structure. Disease codes may depend on coding practices, medications are prescribed in response to severity, and laboratory missingness may reflect clinical judgment. A model may preserve observed correlations while reproducing confounding and access inequities. Synthetic data do not solve bias automatically; they can amplify underrepresented-group errors if sampling or constraints are poorly designed.

Regulatory and ethical guidance increasingly stresses intended use, human oversight, transparency, and postdeployment monitoring. The NIST AI Risk Management Framework [8] provides a general vocabulary for mapping, measuring, and managing risks. In medical settings, additional institutional review, consent or legal authorization, security safeguards, and independent audit may be necessary even when released records are synthetic.

The gap motivating this study is methodological integration. Existing evaluations frequently prioritize either fidelity, model utility, or privacy in isolation. A defensible release decision requires all three, plus clinical consistency and fairness, with explicit fail conditions. The proposed work therefore organizes these strands into a documented protocol and identifies where future real-data experiments are required before any substantive performance claim can be made.

3. Research Methodology

3.1 Study design, cohort definition, and governance

The design is a comparative methodological protocol for patient-level structured electronic health records. A future implementation should define inclusion dates, age limits, index encounter, observation window, target outcome, coding standards, and exclusion criteria before accessing records. Split patients into development (70%), validation (15%), and final test (15%) partitions, stratified by outcome and institution where feasible. All encounters belonging to a person remain in one partition. The final real test partition is never supplied to a generator or used to tune privacy filters.

Data custodians document legal basis, retention, access roles, secure computing environment, and prohibited downstream uses. A data dictionary records field type, units, clinical range, missingness meaning, protected attributes, and intended synthesis status. Highly identifying free text and rare direct identifiers are excluded or processed through a separately validated pipeline.

3.2 End-to-end research flowchart

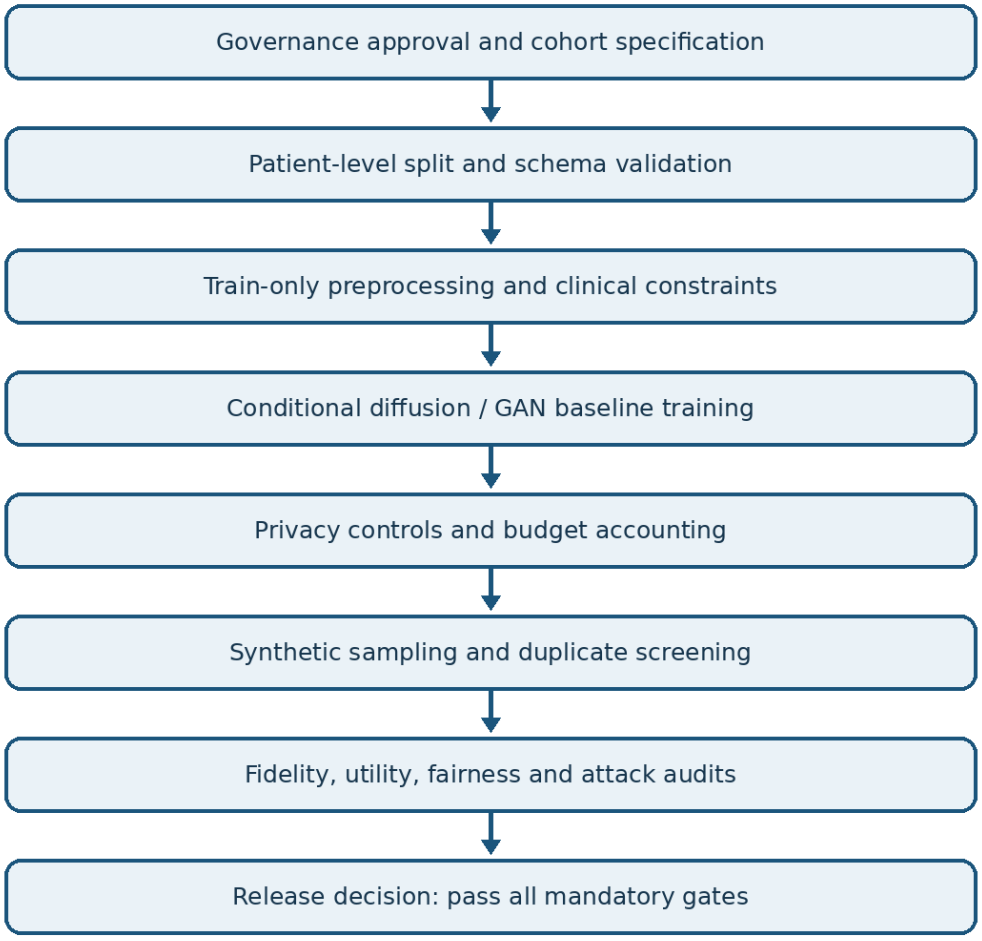

Figure 1. Proposed gated workflow; arrows represent sequential review and not an automatic approval process.

3.3 Representation and conditional synthesis

Encode continuous laboratory values using robust statistics estimated on the training set only. Represent categorical diagnoses with controlled vocabularies and preserve missingness masks as distinct variables. Define conditioning factors such as age band, disease group, and outcome only when the intended release policy permits them. Cap rare categories or group them using clinically approved hierarchies, recording all transformations.

$$x = (v - median(v)) / IQR(v)$$

Here v is an observed continuous value, median(v) is its training-set median, IQR(v) is its interquartile range, and x is the scaled representation. The transformation is inverted after sampling and validated against clinically acceptable ranges.

$$q(z_t \mid z_0) = N(\sqrt{\bar{\alpha}_t}\, z_0, (1 - \bar{\alpha}_t)\, I)$$

Here z_0 denotes the encoded source record, z_t the noisy representation at diffusion step t, $\bar{\alpha}_t$ the cumulative signal-retention factor, I the identity matrix, and N a multivariate normal distribution. Subscript-like symbols are represented with Unicode characters rather than underscores or dashes.

$$L = E[\,||\,\varepsilon - \varepsilon\theta(z_t, t, c)\,||^2\,]$$

The denoising objective L measures squared error between sampled noise ε and the predicted noise εθ conditioned on diffusion time t and permitted cohort descriptor c. The model is selected using validation-only fidelity and utility objectives, never the final real test set.

3.4 Privacy protection and risk accounting

Optionally train with per-patient gradient clipping and Gaussian noise. The unit of protection is a patient, not an encounter. State the adjacency definition and account for every optimization step. Consider several privacy budgets rather than presenting one epsilon as universally safe; an independent privacy reviewer sets the release threshold before inspecting results.

$$\bar{g} = (1 / B)\,\Sigma\, clip(g_i, C) + N(0, \sigma^2\, C^2\, I) / B$$

In this equation g_i is the per-patient gradient, C the clipping norm, B the minibatch size, σ the noise multiplier, and $\bar{g}$ the noisy average gradient. The expression is an implementation schematic; a production accountant must incorporate the actual sampling mechanism and optimization schedule.

$$Pr[M(D) \in S] \leq e^{\varepsilon}\, Pr[M(D') \in S] + \delta$$

Here M is the randomized training or release mechanism, D and D′ are adjacent datasets differing by one patient, S is any measurable output event, ε is the privacy loss parameter, and δ is the additive failure probability. This guarantee applies only when the mechanism and accounting assumptions are satisfied.

Perform exact-match and near-neighbor screens in a secure environment. Evaluate membership inference against balanced member and nonmember sets, attribute inference on sensitive labels, and nearest-neighbor distances relative to a real holdout baseline. Remove obvious copied records, but do not describe post hoc filtering as a substitute for a formal privacy guarantee.

3.5 Statistical, clinical, and downstream utility assessment

Assess marginal fidelity with total variation distance for categorical fields and Wasserstein distance for continuous fields; evaluate pairwise correlation errors and conditional prevalence by subgroup. Report bootstrap confidence intervals. Clinical validators check impossible ages, negative physiologic values, contradictory sex-specific codes where clinically relevant, diagnosis-medication logic, and chronology. These rules are reviewed to avoid excluding legitimate atypical cases.

$$TVD(P, Q) = ½\,\Sigma\,|P(k) - Q(k)|$$

P(k) and Q(k) are the real and synthetic probabilities of category k. Smaller total variation distance indicates closer categorical distributions; it does not itself imply privacy or clinical validity.

$$U = AUROC(TSTR) / AUROC(TRTR)$$

TSTR denotes train on synthetic and test on untouched real data; TRTR denotes train on real development data and test on the same untouched real test set. U is the relative discrimination retention ratio, provided the denominator is positive. Identical model families, tuning budgets, and evaluation partitions are used for fair comparison.

$$ECE = \Sigma\,(n_\beta / N)\,|\,acc(b) - conf(b)\,|$$

ECE is expected calibration error over bins b, where n_β is the number of predictions in bin b, N is total predictions, acc(b) is observed event frequency, and conf(b) is mean predicted risk. Calibration must be reported alongside AUROC and AUPRC for imbalanced clinical outcomes.

3.6 Fairness, robustness, and preregistered release gates

Evaluate age, sex, institution, and clinically relevant protected or vulnerable subgroups where collection and lawful use permit. Compare sensitivity, false-positive rate, calibration, and utility retention with confidence intervals. Prespecify minimum cell sizes to prevent disclosure through subgroup tables. Stress-test shifts in disease prevalence, missingness, and hospital-specific coding. A release is blocked if any critical clinical rule, privacy attack threshold, or mandatory subgroup floor fails, even if aggregate fidelity is high.

$$\Delta TPR = max(TPR_a) - min(TPR_a)$$

TPR_a denotes true-positive rate in subgroup a; ΔTPR is the spread between the highest and lowest subgroup sensitivities. Lower spread is desirable, but should be interpreted together with sample size and disease prevalence.

3.7 Reproducibility and statistical analysis plan

For a real experiment, train at least five independent random seeds for each architecture and privacy condition, recording hardware, software versions, preprocessing code, training epochs, privacy accountant, and seed values. Compute patient-level bootstrap 95% confidence intervals on the untouched test set. Compare paired AUROC values with appropriate paired procedures and adjust for multiple comparisons. Publish code, schema, model card, and synthetic outputs only after approval; never publish source patient records or per-patient attack scores.

4. Results and Discussion: Illustrative Scenario Only

IMPORTANT: The following numerical tables and plots are hypothetical demonstration values created to show a reporting format. No medical dataset was accessed, no generator was trained, and no empirical performance is claimed. The numbers must be replaced with actual measured results before submission as an experimental research paper.

Illustrative model	AUROC	AUPRC	ECE ↓	Mean TVD ↓	Attack AUC ↓
Real-data baseline (TRTR)	0.842	0.418	0.061	—	—
Conditional GAN	0.798	0.365	0.089	0.123	0.62
Conditional diffusion	0.816	0.391	0.074	0.087	0.59
Private	0.794	0.366	0.082	0.109	0.54

diffusion, ε = 8					
Private diffusion, ε = 3	0.761	0.329	0.097	0.151	0.51

Table 1. Hypothetical comparison. Lower attack AUC toward 0.50 suggests weaker membership distinguishability under the specified attack; it does not prove anonymity. The private models demonstrate an illustrative reduction in discrimination as noise increases, alongside a possible utility penalty.

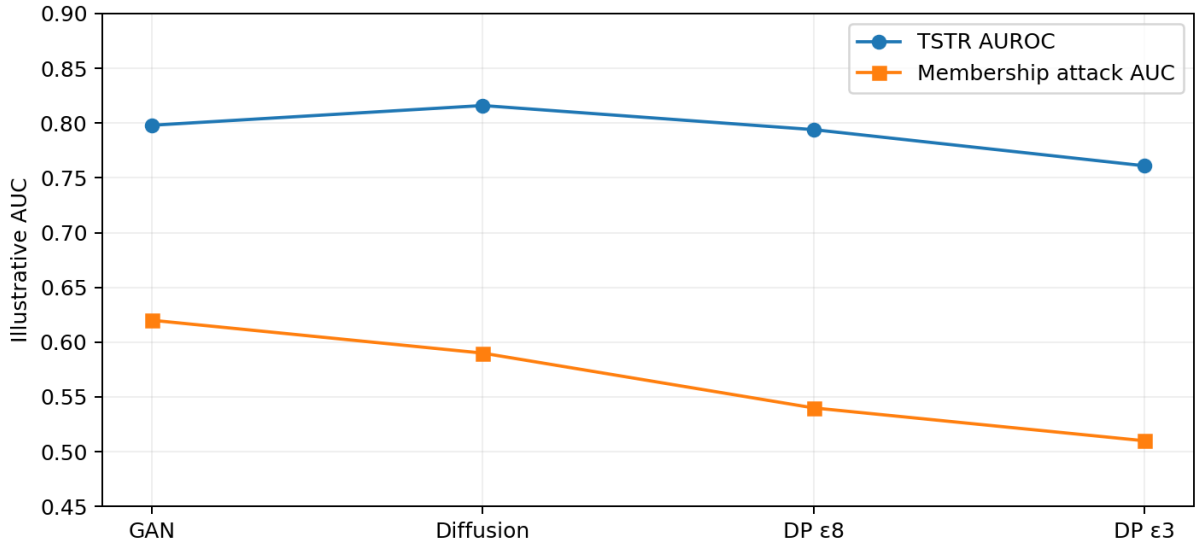

Figure 2. Illustrative tradeoff between predictive discrimination and membership attack performance. Values are hypothetical, not experimental findings.

Illustrative clinical check	**GAN**	**Diffusion**	**DP ε8**	**DP ε3**
Constraint compliance (%)	96.1	98.4	98.1	97.5
Correlation MAE	0.112	0.076	0.092	0.138
Minority subgroup sensitivity	0.68	0.72	0.69	0.63
Utility retention U	0.948	0.969	0.943	0.904

Table 2. Hypothetical clinical consistency and utility indicators. Utility retention is derived from Table 1 by dividing synthetic AUROC by the illustrative TRTR AUROC. A high compliance rate does not guarantee that rare clinical scenarios are represented correctly.

The example suggests how a release committee could weigh several dimensions rather than rank models solely by AUROC. A nonprivate diffusion model may preserve better predictive structure, while a more strongly protected variant may make membership inference less effective. Neither statement is a measured conclusion of this study. In practice, confidence intervals, attack strength, privacy accounting, external validation, and clinical review would determine whether these differences are meaningful.

A crucial limitation of the illustrative example is that it does not simulate the full diversity of medical coding, temporal dependence, institution-specific bias, or attacker auxiliary information. A real study should report subgroup sample sizes, uncertainty bounds, operating-point sensitivity, and external hospital transfer results. Without such evidence, synthetic data should be restricted to low-risk development and educational purposes rather than clinical decision-making.

5. Conclusion

This paper specifies an integrated framework for generating and assessing synthetic medical records using conditional generative AI, optional differential privacy, clinical constraints, and independent release auditing. Its central methodological finding is that privacy, fidelity, and clinical utility must be evaluated as separate but jointly necessary dimensions. The proposed workflow makes patient-level splitting, privacy accounting, attack testing, train-on-synthetic-test-on-real evaluation, subgroup auditing, and clinical sign-off explicit. The numerical example is intentionally illustrative and cannot support claims of observed superiority. Future work should implement the protocol on ethically approved multi-institutional datasets, validate longitudinal consistency, benchmark privacy attacks under realistic auxiliary knowledge, and quantify external clinical utility with uncertainty intervals. Synthetic medical data should supplement, not replace, secure real-world validation.

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