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Generative AI for Automated Clinical Trial Database Lock Readiness

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Abstract: *Database lock is the gate between clinical data management and statistical analysis, and delays at this gate postpone submissions, unblind decisions and, ultimately, patient access to new therapies. Lock readiness is still assessed largely by hand, through checklists, spreadsheets and status meetings in which data managers triage thousands of residual queries, reconciliation discrepancies and coding differences. This paper proposes a governed architecture in which a retrieval-grounded generative language model drafts query resolutions, reconciliation narratives and checklist evidence, a calibrated statistical model forecasts readiness, and trained reviewers remain the accountable decision makers. The architecture is evaluated with two transparent computational experiments, neither of which involves patient data. First, a readiness model fitted to 1,200 synthetic study snapshots reached an AUC of 0.783 on a held-out set, with a Brier score of 0.131 and an expected calibration error of 0.032. Second, a Monte Carlo study of 2,000 simulated lock cycles under stated assumptions estimated a median of 20.2 working days to lock readiness for manual triage and 12.2 days for human-reviewed generative assistance, a 40% reduction, with a residual error-escape rate of 0.67%. A closed-form break-even analysis shows that assistance pays off whenever the draft acceptance probability exceeds 0.14, while safety depends mainly on reviewer vigilance. The findings support a cautious, human-in-the-loop adoption pathway and identify the parameters that a sponsor must measure before deployment.*

Introduction

Database lock marks the moment at which the clinical database for a study is declared complete, consistent and ready to be frozen against further change. After lock, the data are released to statisticians, treatment assignments may be unblinded, and the analyses specified in the statistical analysis plan are executed on a fixed dataset. Because every downstream milestone, including the clinical study report, regulatory dossier and any interim decision that depends on the final data, waits for this event, the interval between the last patient's last visit and database lock is one of the most closely watched metrics in clinical operations [1], [2].Reaching lock is not a single task but a convergence of many.

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All expected data pages must be entered, all queries answered and closed, serious adverse events reconciled between the clinical and safety databases, medical and drug terms coded to the approved dictionary versions, external data such as laboratory and imaging transfers reconciled with the clinical records, protocol deviations reviewed and classified, and the required signatures collected from investigators. Good data management practice describes these activities in checklists and standard operating procedures [3], and the resulting data are expected to conform to the study's data standards [4]. In practice, the final weeks before lock are dominated by repetitive but judgement-laden work: reading an unresolved query and its history, deciding whether the site's answer is adequate, drafting a follow-up or closure comment, and recording the evidence.

Recent progress in generative language models offers a possible way to relieve this burden. Models built on the transformer architecture [5] and trained on very large text corpora have shown a striking ability to summarize, classify and draft text from instructions and a few examples [6]. When coupled with a retrieval component that supplies relevant source documents at generation time, they can produce outputs that are conditioned on, and can cite, a controlled body of knowledge rather than relying on what the model happens to have memorized [7]. Medical applications of such models have attracted considerable attention, accompanied by caution about factual errors and inappropriate confidence [8], [9], [10]. Clinical data management combines the features that make generative models attractive, namely large volumes of semi-structured text and repetitive drafting, with the features that demand restraint: regulatory accountability, patient-safety implications and an expectation that every action is attributable and verifiable.

The central question of this paper is therefore not whether a language model can write a plausible query response, but under what conditions the use of such a model shortens the path to lock without degrading data quality. Answering it requires three things that are seldom combined in the literature: an architecture that places generation inside the existing quality system, a calibrated way of knowing how ready a study actually is, and a quantitative model of the trade-off between time saved and errors that might escape review.

The contributions of this work are fourfold. (i) It specifies a reference architecture for retrieval-grounded generative assistance in lock-readiness activities, including guardrails, routing logic and review controls. (ii) It formulates a calibrated readiness score from routinely available study metrics and evaluates it on a synthetic corpus of 1,200 study snapshots. (iii) It derives closed-form expressions for expected review effort, the break-even draft quality and the residual error-escape rate, and validates them through a Monte Carlo simulation of 2,000 lock cycles. (iv) It reports sensitivity analyses that identify which assumptions drive the benefit and the risk, giving sponsors a checklist of quantities to measure in a pilot. The remainder of the paper is organized as follows: Section II reviews the background, Section III summarizes related work, Section IV describes the methodology, Section V the experimental setup, Section VI the results, Section VII a discussion of implications and limitations, and Section VIII the conclusions.

LITERATURE REVIEW

A. Database lock in the clinical data lifecycle

Clinical data management spans protocol review, data-collection design, data entry and validation, query management, coding, reconciliation and lock. The Society for Clinical Data Management publishes widely used practice guidelines that describe each of these stages and the evidence a lock decision should rest upon [3]. A comprehensive overview of the discipline emphasizes that the quality of the final database is the cumulative result of many small controls, rather than of a single end-of-study review [11]. Data standards such as the Study Data Tabulation Model give the lock a concrete target, since the locked data are expected to be convertible into standardized tabulations with traceable lineage [4].

A pre-lock checklist typically includes items on data completeness, query status, serious adverse event reconciliation, dictionary coding, external data reconciliation, protocol deviation review, audit-trail review and signature status. Organizations commonly add a readiness meeting at which each functional lead reports status and risks, followed by a formal approval from data management, biostatistics, clinical operations and medical review. Although this governance is robust, the information that supports it is assembled manually from several systems, and the responsible leads must interpret it under time pressure. Delays are frequently caused not by a single large problem but by the long tail of small unresolved items whose number is only visible late in the process.

B. Regulatory and quality expectations

The revised international guideline for good clinical practice promotes proportionate, risk-based quality management and requires that computerized systems used in trials be fit for purpose, with data integrity, traceability and appropriate human oversight maintained throughout [1]. Regulations governing electronic records and signatures add requirements for secure, computer-generated audit trails, access control and validation [2]. Any tool that drafts or recommends actions in the lock process falls within this perimeter: its intended use must be defined, its performance must be verified in proportion to the risk it creates, and its outputs must be attributable to a responsible human decision maker. General frameworks for managing the risks of artificial intelligence emphasize the same themes of governance, mapping of context, measurement and ongoing management [12].

C. Generative language models and their limitations

Generative language models learn statistical regularities in text and can be adapted to tasks by prompting. Their usefulness in drafting is matched by well-documented failure modes. The most important for regulated work is hallucination, the generation of fluent statements that are not supported by the source material [13]. Evaluations of models on medical question answering show that performance can be high on average yet uneven across

question types, and that models can express unwarranted certainty [9], [10]. Retrieval-augmented generation mitigates but does not eliminate this problem, because the model may misread, ignore or over-generalize the retrieved passages [7]. Calibration is a related concern: modern neural networks are often over-confident, so that stated confidence cannot be taken at face value without recalibration [14]. These limitations explain why a defensible architecture treats generated text as a proposal that must be grounded, scored and reviewed, never as a decision.

D. Predictive modelling of operational readiness

Predicting whether a study will be ready for lock within a given horizon is a binary probabilistic forecasting problem. Logistic regression remains a standard, interpretable choice for such problems, and its coefficients can be read as the standardized effect of each metric on the log-odds of readiness [15]. Tree-based ensembles such as gradient boosting can capture non-linearities and interactions [16]. Whatever the model, a forecast intended to support decisions should be judged on discrimination, usually summarized by the area under the receiver operating characteristic curve [17], and on probability accuracy and calibration, for which the Brier score [18] and binned calibration error are standard measures. A well-calibrated score is more valuable to a lock manager than a slightly more discriminating but over-confident one, because the manager must decide how much risk to accept on a given date.

RELATED WORK

Work relevant to this study falls into four groups. The first group applies rules and dashboards to lock management. Operational dashboards that aggregate query counts, page completion and reconciliation status are now common, and some organizations define quantitative lock criteria, such as thresholds on open queries per subject. These tools improve visibility but do not interpret unstructured content, and they cannot draft the language needed to close an item. The second group applies classical machine learning to data-quality tasks, for example to prioritize queries, detect anomalies in laboratory values or estimate the risk that a site will generate many discrepancies. Such models have shown that the quality signal in routine metrics can be exploited, but they generally output a score rather than a resolved action.

The third group concerns clinical natural language processing. Sentence embeddings allow short texts to be mapped to vectors whose similarity reflects meaning [19], which makes it possible to retrieve previous resolutions, standard operating procedure sections and data-management plan clauses relevant to a new issue. Large language models have been evaluated on clinical text summarization, question answering and documentation, with promising results in carefully controlled benchmarks and recurring concerns about reliability in deployment [8], [9], [10]. The fourth group is the emerging literature on governance of artificial intelligence in regulated settings, which stresses documentation, human oversight, monitoring for drift and proportionate validation [12]. Combined with the principles of findable, accessible, interoperable and reusable data [20], this literature suggests that generative assistance can be adopted

responsibly if the surrounding controls are explicit.
What is largely absent is a quantitative treatment of the trade-off at the heart of adoption. Existing reports describe capabilities or small pilots but rarely give a transparent model that links the draft acceptance rate, the share of issues suitable for assistance, reviewer vigilance and team capacity to elapsed time and residual error. This paper contributes such a model, together with a calibrated readiness forecast, and makes every assumption explicit so that sponsors can replace it with their own measurements.

METHODOLOGY

A. Reference architecture

The proposed architecture, shown in Figure 1, has two cooperating halves. The upper half is a measurement and forecasting chain. Source systems, including electronic data capture, electronic clinical outcome assessments, central laboratories, safety, coding and randomization systems, feed a readiness data mart that stores periodic snapshots of lock-relevant metrics together with lineage tags identifying the originating system and extraction time. A scoring service converts each snapshot into a calibrated probability that the study will be lock-ready within a stated horizon, and a dashboard presents the score, the contributing domains and a forecast of remaining effort.The lower half is a generation chain. A knowledge base holds the controlled documents that define correct behaviour: standard operating procedures, the data management plan, the statistical analysis plan, the coding conventions and the lock checklist. A retrieval layer indexes these documents and the history of closed issues with embeddings and applies access controls so that a request can only retrieve material the requesting study is entitled to see. A generative agent receives an open issue, the retrieved passages and a structured instruction, and returns a draft resolution, a reconciliation narrative or a completed checklist item with citations. A guardrail layer checks that every factual statement is supported by a citation, redacts personal data, and withholds drafts whose confidence falls below a gate. Human review and governance span both halves: trained data managers accept, edit or reject each draft, every action is logged in the audit trail, and prompts, model versions and retrieval indexes are placed under change control.

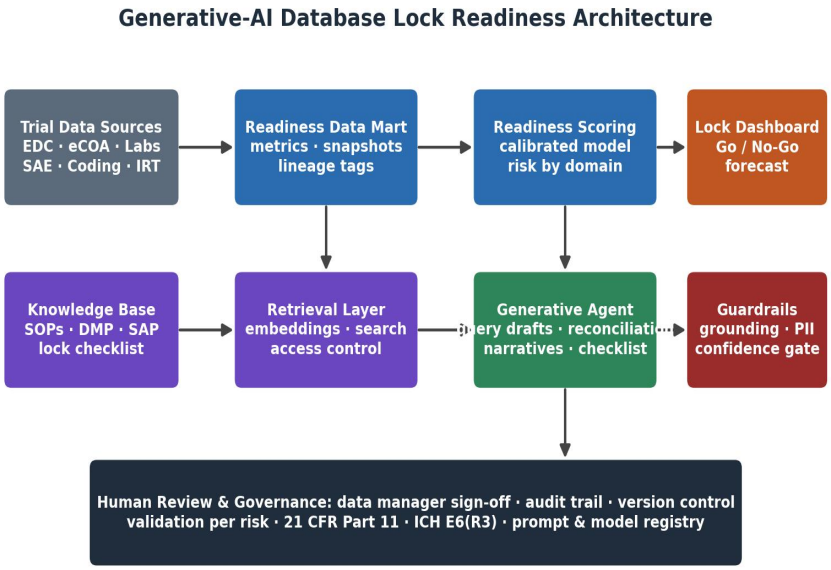


Figure 1: Generative-AI Database Lock Readiness Architecture

B. Readiness score

For study snapshot t, let x_tj denote the j-th readiness metric, such as the percentage of pages with open queries, the percentage of expected pages missing, the number of pending serious adverse event reconciliations, the percentage of terms awaiting coding, the number of unreviewed protocol deviations, the percentage of external records that do not reconcile, and the percentage of outstanding investigator signatures. Each metric is standardized and combined in a logistic model that returns the probability of readiness:

$$S_t = \sigma\left(\beta_0 + \sum_{j=1}^{J} \beta_j z_{tj}\right) = \frac{1}{1+e^{-\eta_t}} \tag{1}$$

$$z_{tj} = \frac{x_{tj} - \mu_j}{s_j} \tag{2}$$

where σ is the logistic function, β are coefficients estimated by maximum likelihood on historical snapshots, and μ_j and s_j are the training mean and standard deviation of metric j. Because the metrics are standardized, the magnitude of a coefficient indicates the relative influence of the metric. A gradient-boosting classifier with default hyper-parameters is fitted as a non-linear comparator. Probability accuracy is summarized by the Brier score and the expected calibration error over B bins, where n_b is the number of snapshots in bin b, with the observed fraction of ready snapshots and the mean predicted probability in that bin compared, and discrimination by the area under the curve, which equals the probability that a randomly chosen ready snapshot receives a higher score than a randomly chosen not-ready snapshot:

$$\text{Brier} = \frac{1}{n}\sum_{i=1}^{n} (\hat{p}_i - y_i)^2 \tag{3}$$

$$\mathrm{ECE} = \sum_{b=1}^{B} \frac{n_b}{n} |\bar{y}_b - \bar{p}_b| \tag{4}$$

$$\mathrm{AUC} = P(\hat{p}^+ > \hat{p}^-) + \tfrac{1}{2} P(\hat{p}^+ = \hat{p}^-) \tag{5}$$

C. Retrieval and grounded generation

Issue text and knowledge-base passages are mapped to dense vectors by a sentence-embedding model, and candidate passages are ranked by cosine similarity between the query vector q and each document vector d [19]:

$$\mathrm{sim}(\mathbf{q}, \mathbf{d}) = \frac{\mathbf{q} \cdot \mathbf{d}}{\|\mathbf{q}\| \, \|\mathbf{d}\|} \tag{6}$$

The top-ranked passages are supplied to the generative agent together with the issue history and an instruction that requires every substantive statement to cite a passage. A grounding score is computed for each draft as the proportion of its claims that are supported by retrieved evidence, where C is the set of claims extracted from the draft and R is the set of claims entailed by the retrieved passages:

$$G = \frac{|C \cap R|}{|C|} \tag{7}$$

Drafts with a grounding score below a configured threshold, drafts that contain claims about the subject's medical status, and drafts that would change a value in the database are never offered as auto-completable; they are routed to manual handling. This design means that the generative component can only propose wording and evidence, while the act of changing data or closing a safety-related item remains a human action.

D. Routing and human review

Figure 2 shows the workflow for a single open issue. An eligibility router classifies the issue by type and risk. Routine items such as requests to confirm a visit date, clarify a unit or close a query whose answer is already documented are eligible for assistance; items involving serious adverse events, unblinding, eligibility criteria or efficacy endpoints are not. For eligible items the agent produces a grounded draft that the reviewer accepts, edits or rejects. A rejected draft costs the reviewer additional time because the item must then be handled manually. A small fraction of incorrect drafts may be accepted by mistake, and this is the mechanism by which an error could escape into the locked database.

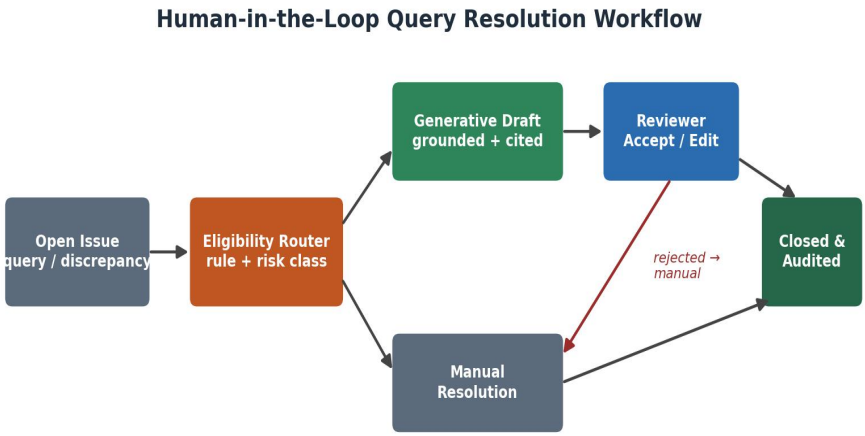


Figure 2: Human-in-the-Loop Query Resolution Workflow

E. Analytical model of effort and risk

Let m denote the mean time to resolve an issue manually, r the mean review time when a draft is accepted, and δ the extra time lost when a draft is rejected and the issue is then handled manually. Let e be the eligible fraction of issues and p the probability that an eligible draft is accepted. The expected handling time per issue under assistance is

$$E[T_i] = e[pr + (1-p)(m+\delta)] + (1-e)m \tag{8}$$

Assistance reduces expected effort whenever $E[T_i] < m$. Setting the bracketed term for eligible issues equal to m and solving for p gives the break-even acceptance probability:

$$p^* = \frac{m+\delta-m}{m+\delta-r} = \frac{\delta}{m+\delta-r} \tag{9}$$

Let γ denote the probability that a reviewer fails to notice an incorrect draft. An incorrect draft arises with probability 1 − p on an eligible issue, so the residual error-escape rate, the expected fraction of all issues that are closed with an incorrect draft, is

$$\varepsilon = e(1-p)\gamma \tag{10}$$

The elapsed time to lock readiness for a study with N open issues, a team of K reviewers each providing h productive hours per day, and a fixed sequential component D_0 that cannot be shortened by parallel work, such as waiting for an external data transfer, is

$$D = D_0 + \frac{\sum_{i=1}^{N} T_i}{K h 60} \tag{11}$$

and the relative improvement from assistance is summarized by the reduction in the median of D across simulated studies:

$$\Delta = 1 - \frac{\text{median}(D_{AI})}{\text{median}(D_{manual})} \tag{12}$$

F. Monte Carlo simulation

The analytical expressions are evaluated and checked by simulation. In each of 2,000 simulated studies the number of open issues N was drawn from a log-normal distribution with a median of 1,500 and a logarithmic standard deviation of 0.35. Manual handling time per issue was log-normal with a median of 22 minutes and a logarithmic standard deviation of 0.5. Under assistance, 75% of issues were eligible; for an eligible issue the draft was accepted with probability 0.82, in which case review took a log-normal time with median 5 minutes, and otherwise the manual time was incurred plus a median of 3 minutes of lost review. Reviewers failed to detect an incorrect draft with probability 0.05. The team comprised six reviewers each providing six productive hours a day, and a fixed component of three working days was added. These values are assumptions, not measurements of any particular model or organization, and they are varied systematically in the sensitivity analyses. A target of ten working days to lock readiness was used as an illustrative benchmark.

EXPERIMENTAL SETUP

A. Synthetic readiness corpus

No patient-level or sponsor data were used. A corpus of 1,200 synthetic study snapshots was generated with a fixed random seed. Each snapshot contained the seven readiness metrics defined above, drawn from gamma or Poisson distributions chosen to give right-skewed, non-negative values with realistic ranges, for example open-query percentages between 0 and 40 and signature backlogs up to 70%. The binary outcome, lock-ready within 14 days, was generated from a logistic model whose true coefficients penalized every backlog metric, with the strongest penalties on open queries, missing pages and pending serious adverse event reconciliations, and with additional Gaussian noise on the linear predictor to mimic unmeasured influences. The resulting prevalence of readiness was 19.4%, reflecting the fact that most snapshots in the final months of a study are not yet ready. The corpus was split at random, stratified by outcome, into 840 training and 360 test snapshots. The logistic model used standardized inputs, and the gradient-boosting model used default settings. All results are reported on the held-out test set. Because the data are synthetic, they demonstrate that the evaluation procedure behaves sensibly and that the metrics carry usable signal; they do not establish how accurately any particular real-world dataset can be forecast.

B. Software and reproducibility

All computations were run on a single Linux virtual machine under Python 3.12. The principal libraries were NumPy [21] for random generation and array computation, and scikit-learn [15] for logistic regression, gradient boosting, calibration curves and evaluation metrics. A single master seed governed data generation, the train-test split and the simulation so that every figure and number in the paper can be reproduced exactly from the scripts. The generative language model and the retrieval layer of the architecture were not executed in this study; their behaviour is represented

in the simulation by the parameters p, e and γ, which is the reason that those parameters are varied widely.

C. Evaluation measures

Readiness forecasts were evaluated by AUC, Brier score, expected calibration error with eight quantile bins, and the precision and recall obtained when snapshots with a predicted probability of at least 0.4 are flagged as likely ready. Simulation outputs were the median and interquartile range of elapsed working days, the proportion of simulated studies meeting the ten-day target, and the mean residual error-escape rate. Sensitivity analyses varied the draft acceptance probability from 0.50 to 0.95, the reviewer miss rate among 0.02, 0.05 and 0.10, and the eligible fraction among 0.25, 0.50, 0.75 and 0.90.

TABLE 1. Simulation Parameters and Baseline Values

Parameter	Symbol	Baseline value
Open issues per study	N	Log-normal, median 1,500, σ = 0.35
Manual time per issue	m	Log-normal, median 22 min, σ = 0.5
Review time, draft accepted	r	Log-normal, median 5 min, σ = 0.4
Extra time, draft rejected	δ	Log-normal, median 3 min, σ = 0.4
Eligible fraction	e	0.75
Draft acceptance probability	p	0.82
Reviewer miss probability	γ	0.05
Reviewers × productive hours	K × h	6 × 6 h per day
Fixed sequential component	D0	3 working days

Parameters are assumptions for simulation and do not describe measured model performance.

RESULTS

A. Readiness forecasting

On the held-out test set of 360 snapshots, the logistic model achieved an AUC of 0.783, a Brier score of 0.131 and an expected calibration error of 0.032. The gradient-boosting comparator achieved an AUC of 0.741, a Brier score of 0.142 and an expected calibration error of 0.038. The simpler model was therefore better on all three measures (Table 2 and Figure 3), which is plausible because the data-generating process was logistic and the sample was modest; with real data and genuine interactions, the ranking could differ. The calibration curve of the logistic model follows the diagonal closely across the eight quantile bins, indicating that a predicted probability of 0.3 corresponds to roughly 30% of such snapshots being ready.

TABLE 2. Readiness Model Performance on Held-Out Test Set

Model	AUC	Brier score	Expected calibration error
Logistic regression	0.783	0.131	0.032
Gradient boosting	0.741	0.142	0.038

Test set n = 360; prevalence of readiness in the full corpus = 19.4%.

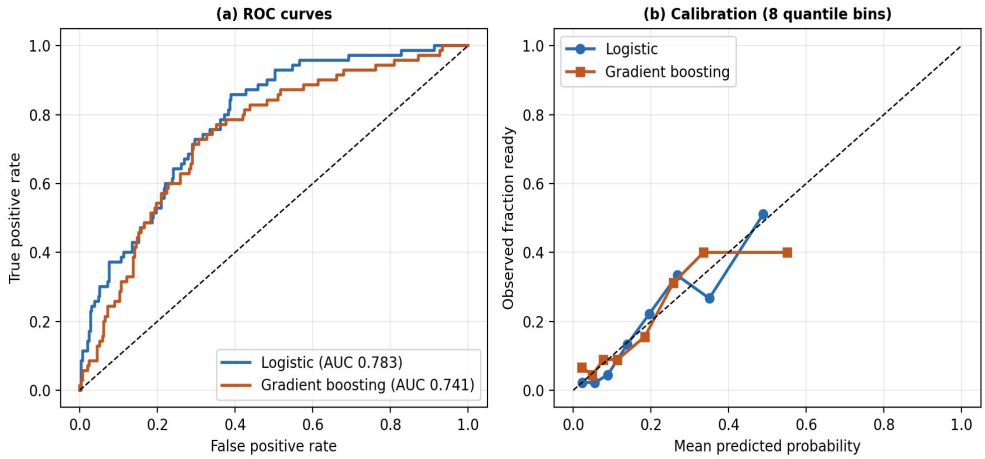


Figure 3: ROC Curves and Calibration of the Readiness Models

The standardized logistic coefficients are listed in Table 3. All were negative, as expected, since every backlog metric lowers the odds of readiness. The percentage of pages with open queries had the largest effect (-0.85 per standard deviation), followed by pending serious adverse event reconciliations (-0.56) and missing pages (-0.51). Unreviewed protocol deviations (-0.39) and external data mismatches (-0.28) had intermediate effects, whereas signature backlog (-0.20) and coding backlog (-0.14) were the weakest. The ordering is consistent with the generating model and with operational experience that open queries and safety reconciliation are the usual critical-path items. When snapshots with a predicted probability of at least 0.4 were flagged as likely ready, 42 of 360 were flagged, with a precision of 50% and a recall of 30%. The modest recall reflects the low prevalence of readiness and the deliberate conservatism of a threshold chosen to limit false assurance.

TABLE 3. Standardized Logistic Regression Coefficients (Log-Odds per SD)

Readiness metric	Coefficient
Pages with open queries (%)	-0.85
SAE reconciliations pending (count)	-0.56
Expected pages missing (%)	-0.51
Protocol deviations unreviewed (count)	-0.39
External data mismatch (%)	-0.28
Investigator signatures pending (%)	-0.20
Coding backlog (%)	-0.14

B. Simulated time to lock readiness

Under the baseline assumptions, the manual process required a median of 20.2 working days to reach lock readiness (interquartile range 16.5 to 24.5), whereas human-reviewed generative assistance required a median of 12.2 days (10.2 to 14.6). The relative reduction in the median was 39.6%. The proportion of simulated studies reaching readiness within the ten-day benchmark rose from 0.6% to 22.2%. The distributions in Figure 4 show that assistance not only shifts the centre but also narrows the spread,

because a smaller and less variable total workload makes the elapsed time less sensitive to the number of open issues. The three-day sequential component set a floor that no amount of drafting assistance could remove, which underlines that process delays unrelated to workload, such as waiting for external transfers, require separate remedies.

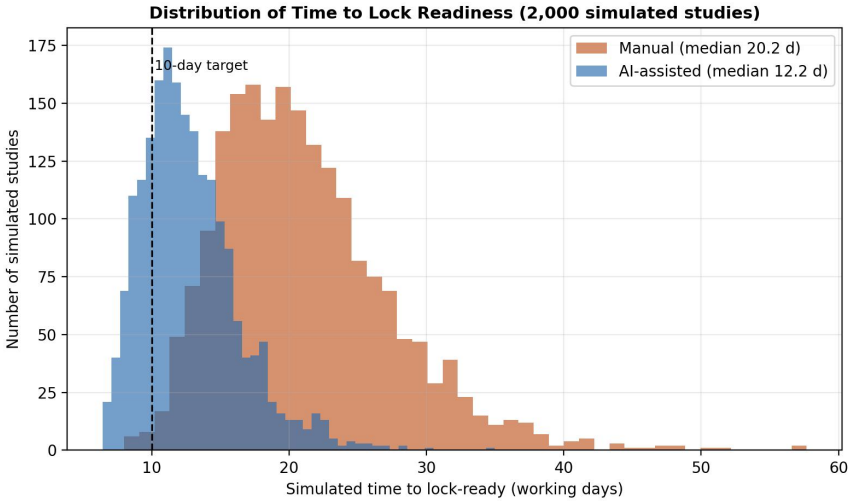


Figure 4: Simulated Distribution of Time to Lock Readiness, Manual versus AI-Assisted

C. Break-even and safety

With the baseline timing parameters the mean manual time per issue was 24.9 minutes, the mean accepted-draft review time 5.4 minutes and the mean rejected-draft time 28.2 minutes. Substituting these means in the break-even expression gives $p^* = 0.14$: on eligible issues, assistance reduces effort whenever more than about one draft in seven is acceptable. This is a low bar, which is why the time benefit is robust to quite weak draft quality. The safety consideration is different. At the baseline acceptance probability of 0.82, eligible fraction of 0.75 and miss probability of 0.05, the mean residual error-escape rate was 0.67% of issues, or roughly seven in every thousand. Whether such a rate is acceptable cannot be decided from time savings; it depends on the severity of the errors that could escape and on the other layers of control that follow, such as downstream edit checks, statistical review and the pre-lock audit.

D. Sensitivity analyses

Figure 5 and Table 4 summarize the sensitivity of cycle time and error escape to draft quality. As the acceptance probability rose from 0.50 to 0.95, the median time to readiness fell from 16.4 to 10.9 working days, and the escape rate at a miss probability of 0.05 fell from 1.86% to 0.18%. Because escape is proportional to the product of the miss probability and the share of incorrect drafts, doubling reviewer vigilance, from a miss probability of 0.10 to 0.05, halves the escape rate at any draft quality, an effect as large as a very substantial improvement in the model itself. The eligible fraction proved to be the most influential determinant of the time benefit: the median time was 17.2 days when only 25% of issues were eligible, 14.5 days

at 50%, 12.0 days at 75% and 10.4 days at 90%.

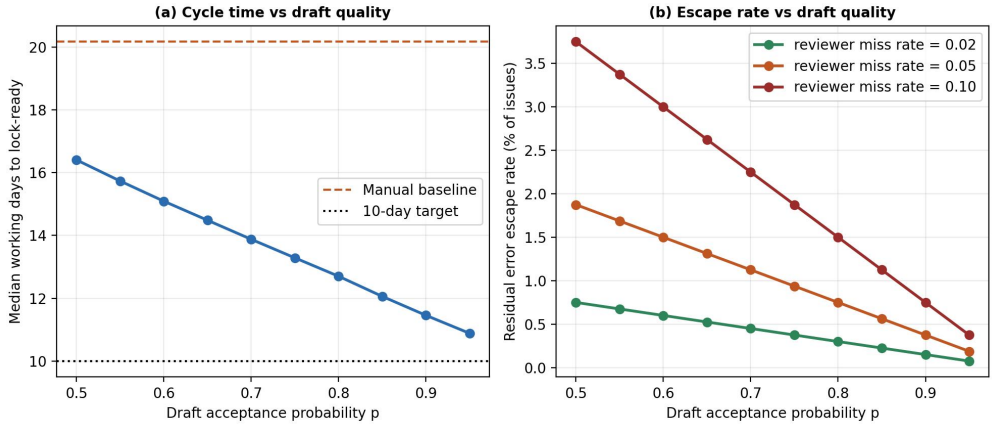


Figure 5: Sensitivity of Cycle Time and Residual Error Escape to Draft Acceptance Probability

TABLE 4. Median Time to Lock Readiness by Eligible Fraction (p = 0.82)

Eligible fraction e	Median working days
0.25	17.2
0.50	14.5
0.75	12.0
0.90	10.4

Manual baseline median = 20.2 days.

DISCUSSION

Three messages emerge from the experiments. First, the economics of assistance are favourable under a wide range of assumptions, but the favourable result depends most strongly on a quantity that is rarely discussed in enthusiastic accounts of generative technology, namely the share of issues that are suitable for assistance at all. Raising the eligible fraction from 25% to 90% reduced the median cycle time by more than the entire effect of changing the draft acceptance probability from 0.50 to 0.95. In practical terms, a sponsor should invest first in characterizing and standardizing the routine issue types that dominate the late-stage workload and in building good retrieval material for them, rather than in pursuing marginal improvements in the generative model.

Second, safety and speed are governed by different parameters. Draft acceptance drives time, whereas the error-escape rate is the product of draft error and reviewer miss probability, so that human vigilance carries as much weight as model accuracy. This has direct implications for the design of review. Reviewers should be shown the evidence cited by the draft rather than only the draft; the interface should make rejection effortless, so that rejection is not discouraged by additional clicks; and sampling-based secondary review should be applied to accepted drafts, so that the miss probability can be estimated and monitored over time. An organization that cannot measure γ cannot claim to control the risk, and the simulation shows how quickly the escape rate grows if vigilance wanes.

Third, calibrated forecasting complements generation. A readiness score

does not draft anything, but it tells a lock manager where to direct the generative effort and when additional resources are needed, and it provides an objective measure of progress. The synthetic experiment showed that even a simple logistic model on seven metrics can be well calibrated, and it demonstrated the usefulness of reporting calibration alongside discrimination. In real deployments the score should be recalibrated periodically, because changes in the mix of studies, in electronic data capture design or in team practice can shift the relationship between metrics and outcomes.

Governance determines whether these benefits can be realized in a regulated setting. The intended use of the generative component should be defined narrowly, for example drafting query closure comments for eligible issue types, and validation should be proportionate to the risk it creates, using representative test sets, acceptance criteria for grounding and citation accuracy, and documented performance in a pilot before production use. Prompts, model versions, retrieval indexes and routing rules should be under change control, with monitoring for drift. Every accepted draft should be attributable to the reviewer who accepted it, and the audit trail should record the evidence presented. Confidentiality needs equal attention: personal data must be redacted before text is sent to any model, and models should run in environments that meet the sponsor's data-protection obligations.

The study has several limitations. The readiness corpus is synthetic and generated from a logistic process, which favours the logistic model and cannot reveal how well real-world metrics predict lock timing. The simulation relies on assumed distributions and parameters, and its outputs are conditional on them; in particular, no generative model was run, and the draft acceptance probability, the eligible fraction and the reviewer miss probability must be measured in a pilot before any numerical claim is transferred to practice. The simulation treats issues as independent and reviewers as interchangeable, whereas real issues cluster by site and type, and reviewer skill varies. It also omits second-order effects such as the possibility that routine assistance changes how sites answer queries, or that reviewers become complacent over time. Finally, the quality of the final database was represented only by the error-escape rate, without modelling the severity of errors or the likelihood that downstream controls would catch them.

Future work will therefore proceed in four directions: measuring acceptance, eligibility and miss probabilities in a controlled pilot on closed studies, where the true resolution is known; extending the simulation with clustered issues, heterogeneous reviewers and complacency dynamics; evaluating readiness forecasting on de-identified operational data with temporal validation; and developing standard validation protocols for generative components in data-management workflows.

CONCLUSION

This paper presented a governed architecture in which a retrieval-grounded generative model proposes, a calibrated statistical model forecasts and trained reviewers decide, and it evaluated the architecture through a synthetic readiness corpus and a transparent Monte Carlo model of lock cycles. The readiness model reached an AUC of 0.783 with good calibration

on synthetic data, and the simulation estimated a 40% reduction in median time to lock readiness, from 20.2 to 12.2 working days, with a residual error-escape rate of 0.67% under stated assumptions. The break-even draft acceptance probability of only 0.14 indicates that time savings are robust, while the escape-rate analysis shows that safety rests on reviewer vigilance and on keeping sensitive issue types out of the assisted route. Sponsors considering adoption should therefore measure the eligible fraction, the draft acceptance probability and the reviewer miss probability in a controlled pilot, validate the generative component in proportion to its risk, and retain human accountability for every lock decision. Used in this way, generative AI can shorten the path to database lock without weakening the integrity of the data on which regulatory decisions depend.

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