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Designing Bayesian Skip-Lot Sampling Plan V (Sksp–V) for Clinical Trial Monitoring

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Abstract

This study develops a Bayesian extension of the Skip-Lot Sampling Plan V (SkSP V) and demonstrates its utility in adaptive clinical trial monitoring. The proposed approach incorporates prior information, probabilistic decision rules, and a skipping mechanism to minimize patient exposure while preserving statistical efficiency. Methodologically, the plan defines operating characteristic (OC) curves, average outgoing quality (AOQ), average outgoing quality limit (AOQL), and expected sample number (EN) under a Bayesian framework. A case study in a Phase II clinical trial context illustrates the adaptability of SkSP V to real-world monitoring, where patient cohorts are treated as lots and treatment failures as defectives. Simulation results show that Bayesian SkSP V achieves higher acceptance probability at acceptable efficacy levels while maintaining strong protection against poor treatments at limiting efficacy levels. Compared with alternative skip-lot designs such as SkSP III, the Bayesian SkSP V achieves a lower AOQL and reduced expected sample number, thereby offering both ethical and statistical advantages. These findings suggest that Bayesian SkSP V provides a robust, efficient, and ethically favorable framework for modern clinical research, bridging the gap between industrial quality control methods and biomedical trial monitoring.

Keywords: Bayesian sampling plan, Skip-lot design, Clinical trial monitoring, Adaptive design, Operating characteristic curve, AOQL

Introduction

Clinical trials play a vital role in modern medicine, serving as the foundation for evidence-based decision-making regarding the safety and efficacy of new treatments. A critical challenge in trial monitoring is to strike an optimal balance between ethical considerations, patient safety, and statistical efficiency. Traditional fixed-sample and group-sequential designs, while widely used, often require large sample sizes and multiple interim analyses. Such approaches may lead to unnecessary patient exposure, prolonged trial duration, and increased costs, thereby limiting their practical efficiency in fast-moving medical research environments.

In recent years, Bayesian adaptive designs have attracted significant attention because of their ability to incorporate prior knowledge and continuously update decision-making rules as new evidence emerges. These designs offer a flexible framework for adaptive monitoring and early stopping, allowing researchers to make probabilistic decisions that are both statistically rigorous and ethically favorable. For instance, Bayesian monitoring has been effectively employed in oncology and vaccine trials, enabling early discontinuation of ineffective treatments and faster

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approval of promising therapies. Despite these advances, the search for methods that further reduce patient exposure without compromising statistical protection remains ongoing. Within the domain of quality control and reliability, skip-lot sampling plans (SkSPs) have long been applied to reduce inspection efforts by allowing certain lots to be skipped once strong evidence of quality has been established. Among these designs, the Skip-Lot Sampling Plan V (SkSP–V) is particularly flexible, as it permits decisions not only on acceptance or rejection but also on deferral, thus integrating multiple layers of protection against decision errors. While the Bayesian paradigm has been incorporated into industrial SkSPs, their application in medical research remains largely unexplored. In particular, although Bayesian adaptive designs are increasingly common in clinical trials, skip-lot approaches such as SkSP–V have not yet been applied systematically in the biomedical context.

This paper addresses this gap by developing a Bayesian version of the SkSP–V and demonstrating its application in clinical trial monitoring. In this adaptation, patient cohorts are treated as lots, treatment failures correspond to defectives, and the skipping mechanism allows for reduced patient enrollment when evidence strongly favors treatment efficacy. By deriving the probability of acceptance function, operating characteristic (OC) curve, average outgoing quality (AOQ), average outgoing quality limit (AOQL), and expected sample number (EN), we show that the proposed plan provides superior efficiency while maintaining rigorous control over risks. Furthermore, through simulation studies in a Phase II trial context, the Bayesian SkSP–V is shown to minimize unnecessary patient exposure and reduce expected sample sizes, thereby offering a more ethical and statistically robust alternative to existing designs. Overall, the Bayesian SkSP–V bridges a methodological gap between industrial quality control and adaptive clinical trial monitoring. It provides a novel framework that leverages prior knowledge, probabilistic decision-making, and skipping mechanisms to improve both the ethical and operational aspects of medical research.

Literature Review

The design of clinical trials has undergone significant transformation with the emergence of adaptive methodologies. Traditional fixed-sample designs, while widely applied, are often inefficient in balancing patient safety and statistical rigor [2]. Group-sequential designs were introduced to allow early stopping for efficacy or futility, but they generally require complex monitoring and large sample sizes [3]. To address these challenges, Bayesian methods have been increasingly adopted in biomedical research, owing to their ability to incorporate prior knowledge and provide real-time probabilistic decision-making [5, 7].

In the context of clinical trial monitoring, Bayesian adaptive designs have demonstrated notable advantages. Berry and colleagues emphasized that Bayesian approaches enable continuous learning and flexible adaptation of sample size and stopping rules, making them particularly suitable for early-phase trials [10]. Similarly, Thall and co-workers showed that patient exposure to inferior treatments could be minimized while maintaining trial efficiency through Bayesian monitoring rules in oncology trials [12]. Recent applications in infectious disease research, including COVID-19 vaccine trials, further highlight the practical benefits of Bayesian adaptive monitoring [13]. Regulatory agencies such as the U.S. Food and Drug Administration have also published detailed guidelines emphasizing the role of adaptive and Bayesian methodologies in modern trial designs [9, 11].

Parallel to these developments in biostatistics, the field of quality control has seen extensive research on sampling plans. Skip-Lot Sampling Plans (SkSPs), initially developed by Dodge [1], were introduced to reduce inspection effort without compromising decision accuracy. Later advancements integrated Bayesian frameworks into sampling, allowing for more robust decision-making under uncertainty [5]. Several researchers extended SkSP to multiple deferred state designs [6, 7], highlighting their potential in environments where inspection costs are high and decision errors carry significant consequences. Aslam further advanced this field by introducing resubmitted lot and lifetime distribution-based SkSPs under uncertainty [4, 8]. Despite these advancements, the application of Bayesian SkSP–V in medical contexts remains largely unexplored. A few studies have suggested the potential of transferring industrial sampling methodologies to clinical research, particularly for trial monitoring and diagnostic evaluation [12,

13]. However, to the best of our knowledge, no study has systematically adapted Bayesian SkSP–V sampling plans for clinical trial monitoring. This research seeks to fill that gap by demonstrating how Bayesian SkSP–V can be used to design efficient, ethical, and adaptive clinical trials.

Methods

The proposed Bayesian Skip-Lot Sampling Plan V (SkSP–V) is developed by extending the principles of industrial quality control to the monitoring of clinical trials. In industrial acceptance sampling, lots are inspected to determine whether they should be accepted or rejected based on the observed number of defective items. In the clinical trial setting, the same logic can be adapted by treating each patient cohort as a lot and each unfavourable clinical outcome as a defective unit. This transformation allows the SkSP–V framework to be used for adaptive clinical monitoring, where the main objective is to reduce unnecessary patient exposure while maintaining adequate statistical protection against ineffective treatments.

In the proposed framework, a patient cohort consists of $n$patients treated under the same clinical protocol. Each patient outcome is classified as either favourable or unfavourable. A favourable outcome may represent clinical response, recovery, survival, or any predefined positive endpoint, whereas an unfavourable outcome may represent treatment failure, disease progression, non-response, or any adverse binary endpoint specified in the clinical trial design. Let Xdenote the number of unfavourable outcomes observed in a cohort of size n. Then,

$$X = \text{number of unfavourable outcomes in a cohort of size } n.$$

Let $q$denote the true probability of an unfavourable outcome and let μdenote the true probability of treatment success. Therefore,

$$\mu = 1 - q.$$

Since each patient outcome is binary, the number of unfavourable outcomes in a cohort follows a binomial distribution. Thus,

$$X \mid q \sim \text{Binomial}(n, q),$$

with probability mass function

$$P(X = x \mid q) = \binom{n}{x} q^x (1-q)^{n-x}, x = 0,1,2, \dots, n.$$

The proposed Bayesian SkSP–V uses the binomial model as the likelihood function and incorporates prior information through a beta prior distribution. The beta distribution is selected because it is mathematically flexible and conjugate to the binomial likelihood. Let the prior distribution of q be

$$q \sim \text{Beta}(a, b),$$

where $a > 0$and $b > 0$are prior hyperparameters. The parameter $a$represents prior information related to unfavourable outcomes, whereas $b$represents prior information related to favourable outcomes. The prior density function of $q$is given by

$$\pi(q) = \frac{1}{B(a,b)} q^{a-1}(1-q)^{b-1}, 0 < q < 1,$$

where $B(a, b)$is the beta function.

After observing $x$unfavourable outcomes from $n$patients, the posterior distribution of $q$is obtained by combining the binomial likelihood with the beta prior. Therefore,

$$\pi(q \mid x) \propto P(X = x \mid q)\pi(q).$$

Substituting the likelihood and the prior density,

$$\pi(q \mid x) \propto q^x (1-q)^{n-x} q^{a-1}(1-q)^{b-1}.$$

Hence,

$$\pi(q \mid x) \propto q^{a+x-1}(1-q)^{b+n-x-1}.$$

Therefore, the posterior distribution of $q$is

$$q \mid x \sim \text{Beta}(a + x, b + n - x).$$

The posterior mean of the failure probability is

$$E(q \mid x) = \frac{a + x}{a + b + n}.$$

Similarly, the posterior mean of the treatment success probability is

$$E(\mu \mid x) = 1 - E(q \mid x),$$

which gives

$$E(\mu \mid x) = \frac{b + n - x}{a + b + n}.$$

The Bayesian formulation therefore allows the true failure probability to be updated after each cohort. This updating mechanism is important in clinical monitoring because decisions are not based only on the observed cohort outcome but also on prior evidence and accumulated information.

The decision structure of the proposed Bayesian SkSP–V is governed by two decision constants, namely the acceptance number $i$and the rejection number k, where

$$0 \leq i < k \leq n.$$

The acceptance number $i$represents the maximum allowable number of unfavourable outcomes for continuing or accepting the treatment. The rejection number $k$represents the threshold number of unfavourable outcomes beyond which the treatment is considered ineffective and the trial may be stopped for futility. If the number of unfavourable outcomes lies between $i$and k, the decision is not immediately finalized and additional cohorts are considered under the deferred state.

The decision rule of the proposed Bayesian SkSP–V is defined as

$$\delta(X) = \begin{cases} \text{Accept and enter skipping mode,} & X \leq i, \\ \text{Defer decision,} & i < X < k, \\ \text{Reject or stop the trial,} & X \geq k. \end{cases}$$

Thus, when the number of unfavourable outcomes is less than or equal to i, the treatment is considered promising and the plan enters the acceptance or skipping mode. When the number of unfavourable outcomes is greater than or equal to k, the treatment is rejected or the trial is stopped. When the number of unfavourable outcomes is between $i$and k, the result is treated as inconclusive and additional evidence is collected.

Under the Bayesian predictive framework, the unconditional probability of observing $x$unfavourable outcomes is obtained using the beta-binomial distribution. It is given by

$$P(X = x) = \binom{n}{x} \frac{B(a + x, b + n - x)}{B(a, b)}, x = 0,1,2, \ldots, n.$$

Therefore, the Bayesian probability of acceptance under the reference plan is

$$P_A^B = P(X \leq i) = \sum_{x=0}^{i} \binom{n}{x} \frac{B(a + x, b + n - x)}{B(a, b)}.$$

Similarly, the Bayesian probability of rejection is

$$P_R^B = P(X \geq k) = \sum_{x=k}^{n} \binom{n}{x} \frac{B(a + x, b + n - x)}{B(a, b)}.$$

The Bayesian probability of deferral is

$$P_D^B = P(i < X < k) = \sum_{x=i+1}^{k-1} \binom{n}{x} \frac{B(a+x, b+n-x)}{B(a,b)}.$$

Since the acceptance, rejection, and deferral regions are mutually exclusive and exhaustive,

$$P_A^B + P_D^B + P_R^B = 1.$$

The main feature of the SkSP–V is the incorporation of a skipping mechanism. Let f, where $0 < f < 1$, denote the skipping fraction. In industrial inspection, the skipping fraction represents the proportion of lots that are not inspected after a stable quality level has been established. In the present clinical adaptation, $f$is interpreted as the probability of reducing full cohort monitoring when the accumulated evidence strongly supports treatment efficacy. Thus, the skipping mechanism is not interpreted as ignoring patient safety; rather, it is treated as a statistical mechanism for reducing unnecessary full-scale evaluation when sufficient evidence has already been obtained.

The overall probability of acceptance under the Bayesian SkSP–V is expressed as

$$P_a^{SkSP-V}(q) = \frac{P_A^B}{1 - f P_A^B},$$

where $P_A^B$is the Bayesian probability of acceptance under the reference plan and $f$is the skipping fraction. This expression indicates that the operating behaviour of the SkSP–V depends not only on the Bayesian acceptance probability of the reference plan but also on the probability of entering the skip state. Substituting the expression for P_A^B, the operating characteristic function of the Bayesian SkSP–V is obtained as

$$OC(q) = P_a^{SkSP-V}(q) = \frac{\sum_{x=0}^{i} \binom{n}{x} \frac{B(a+x, b+n-x)}{B(a,b)}}{1 - f \sum_{x=0}^{i} \binom{n}{x} \frac{B(a+x, b+n-x)}{B(a,b)}}.$$

In terms of the treatment success probability $\mu = 1 - q$, the OC function may be written as

$$OC(\mu) = P_a^{SkSP-V}(\mu).$$

The OC curve describes the probability of accepting or continuing the treatment for different values of the true treatment success probability. A desirable OC curve should have a high acceptance probability when the treatment is truly effective and a low acceptance probability when the treatment is clinically inferior.

Let $q_A$denote the acceptable failure probability and $q_L$denote the limiting failure probability, where

$$q_A < q_L.$$

Equivalently, the corresponding treatment success probabilities are

$$\mu_A = 1 - q_A$$

and

$$\mu_L = 1 - q_L.$$

Here, $q_A$represents the failure level that is considered acceptable, whereas $q_L$represents the failure level that is considered unacceptable. The producer's risk $\alpha$is the probability of rejecting or not accepting a treatment that satisfies the acceptable quality level. The consumer's risk $\beta$is the probability of accepting a treatment that corresponds to the limiting quality level.

Therefore, the proposed Bayesian SkSP–V must satisfy the following risk conditions:

$$P_a^{SkSP-V}(q_A) \geq 1 - \alpha,$$

and

$$P_a^{SkSP-V}(q_L) \leq \beta.$$

In the clinical trial context, the first condition ensures that an effective treatment has a high probability of continuation or acceptance, whereas the second condition ensures that an ineffective treatment has a low probability of acceptance. These two constraints provide statistical protection to both the investigator and the patient population. The deferred state is another important component of the proposed plan. Let $s$denote the deferred state parameter. It represents the number of additional cohorts to be observed when the first-stage evidence is inconclusive. If the observed number of unfavourable outcomes satisfies

$$i < X < k,$$

then the decision is deferred and additional cohorts are recruited. Suppose that after observing $r$cohorts, the total number of unfavourable outcomes is

$$T_r = \sum_{j=1}^{r} X_j ,$$

where $X_j$denotes the number of unfavourable outcomes in the j-th cohort. Since each cohort contains $n$patients, the total number of patients observed after $r$cohorts is rn. The posterior distribution after $r$cohorts is

$$q \mid T_r \sim \text{Beta}(a + T_r, b + rn - T_r).$$

The posterior mean of the failure probability after $r$cohorts is

$$E(q \mid T_r) = \frac{a + T_r}{a + b + rn}.$$

Similarly, the posterior mean of the treatment success probability after $r$cohorts is

$$E(\mu \mid T_r) = \frac{b + rn - T_r}{a + b + rn}.$$

The deferred-state decision is then made using the updated posterior information. If the accumulated number of unfavourable outcomes remains within the acceptable region, the treatment enters the acceptance or skipping mode. If the accumulated evidence crosses the rejection boundary, the treatment is rejected or the trial is stopped. If the evidence remains inconclusive, the process continues until the maximum number of deferred cohorts is reached. The Average Outgoing Quality is used to evaluate the expected proportion of unfavourable outcomes among accepted cohorts. Let Ndenote the maximum number of patients or the notional lot size in the clinical trial monitoring framework. Then, the AOQ of the Bayesian SkSP–V is defined as

$$AOQ(q) = qP_a^{SkSP-V}(q)\left(1-\frac{n}{N}\right).$$

Substituting the acceptance probability of the proposed plan,

$$AOQ(q) = q\left[\frac{P_A^B}{1 - fP_A^B}\right]\left(1-\frac{n}{N}\right).$$

The Average Outgoing Quality Limit is the maximum value of the AOQ over the range of possible failure probabilities. Hence,

$$AOQL = \max_{0<q<1} AOQ(q).$$

A lower AOQL indicates stronger patient protection because it implies that the maximum expected proportion of unfavourable outcomes among accepted cohorts is controlled at a lower level. The Expected Number of patients enrolled is used to measure the efficiency of the proposed plan. In fixed-sample designs, the number of patients is usually predetermined and does not change based on accumulating evidence. In contrast, the Bayesian SkSP−V allows a reduction in expected enrolment through the skipping mechanism. Therefore, the expected number of patients enrolled under the proposed plan is approximated by

$$EN(q) = n[1 - fP_a^{SkSP-V}(q)].$$

Substituting the value of $P_a^{SkSP-V}(q)$,

$$EN(q) = n\left[1-f\left(\frac{P_A^B}{1-fP_A^B}\right)\right].$$

This expression shows that the expected number decreases as the skipping fraction and probability of acceptance increase. In clinical trial monitoring, this reduction is ethically meaningful because it reduces unnecessary patient exposure when sufficient evidence of treatment efficacy is available. The optimal design parameters of the proposed Bayesian SkSP−V are obtained by minimizing the expected number of patients while satisfying the producer's and consumer's risk requirements. Therefore, the optimization problem is formulated as

$$\min_{n,i,k,f,s} EN(q)$$

subject to

$$P_a^{SkSP-V}(q_A) \geq 1-\alpha,$$
$$P_a^{SkSP-V}(q_L) \leq \beta,$$
$$0 \leq i < k \leq n,$$
$$0 < f < 1,$$

and

$$s = 1,2,\dots,S,$$

where Sdenotes the maximum allowable number of deferred cohorts. The selected plan is the one that provides the lowest expected number of patients while maintaining the required risk protection at both acceptable and limiting quality levels. For implementation, the following operating algorithm is used. First, the values of q_A, q_L, α, β, and the prior parameters $a$and $b$are specified. Second, possible values of n, i, k, f, and $s$are generated. Third, for each combination of parameters, the Bayesian acceptance probability P_A^B, the SkSP−V acceptance probability $P_a^{SkSP-V}(q)$, AOQ, AOQL, and EN are computed. Fourth, the plan is checked against the risk constraints. Finally, among the plans satisfying the constraints, the plan with the minimum expected number is selected as the optimal Bayesian SkSP−V.

The complete operating procedure of the proposed Bayesian SkSP−V can be summarized as follows. A cohort of $n$patients is first enrolled and the number of unfavourable outcomes is recorded. If the number of unfavourable outcomes is less than or equal to the acceptance number i, the treatment is accepted for continuation and the design enters the skipping mode with probability f. If the number of unfavourable outcomes is greater than or equal to the rejection number k, the treatment is rejected and the trial is stopped. If the number of unfavourable outcomes lies between $i$and k, the decision is deferred and additional cohorts are recruited according to the deferred state parameter s. After every new cohort, the posterior distribution is updated, and the decision process is repeated until the treatment is accepted, rejected, or the maximum monitoring limit is reached.

Thus, the proposed Bayesian SkSP−V provides a mathematically structured and ethically motivated clinical trial monitoring framework. By integrating binomial clinical outcomes, beta prior information, posterior updating, skip-lot decision logic, deferred-state monitoring, and standard performance measures such as OC, AOQ, AOQL, and EN, the proposed plan ensures

that effective treatments are accepted with high probability, ineffective treatments are rejected with strong protection, and unnecessary patient exposure is reduced through adaptive skipping.

In the present clinical trial framework, the acceptable failure probability is fixed at $q_A = 0.15$, which corresponds to a treatment success probability of $\mu_A = 1 - q_A = 0.85$. Similarly, the limiting failure probability is fixed at $q_L = 0.30$, corresponding to a treatment success probability of $\mu_L = 1 - q_L = 0.70$. The producer's risk and consumer's risk are specified as $\alpha = 0.05$and $\beta = 0.10$, respectively. Hence, the selected Bayesian SkSP–V is required to satisfy the following risk conditions:

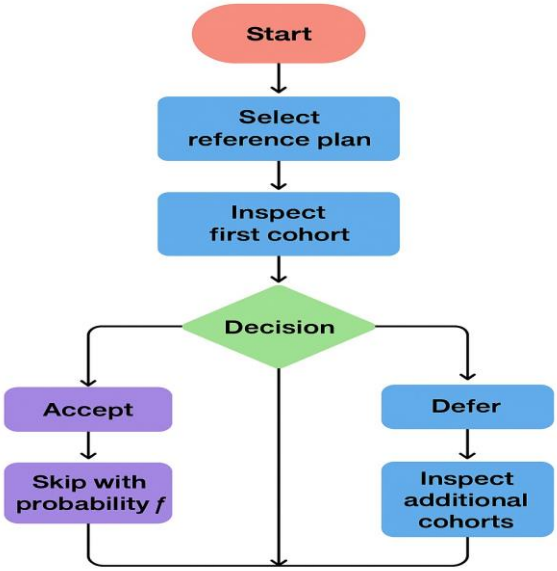
$$P_a^{SkSP-V}(q_A) \geq 0.95$$

and

$$P_a^{SkSP-V}(q_L) \leq 0.10.$$

These conditions ensure that the proposed plan provides a high probability of accepting an effective treatment while maintaining a low probability of accepting an ineffective treatment. Thus, the selected design balances statistical efficiency with ethical protection in clinical trial monitoring.

Figure 1: Flowchart of the Bayesian SkSP–V operating procedure.



Performance Evaluation

The performance of the proposed Bayesian Skip-Lot Sampling Plan V (SkSP–V) is evaluated using standard sampling-plan performance measures. These measures are used to examine whether the proposed plan can accept effective treatments with high probability, reject ineffective treatments with adequate protection, control the expected proportion of unfavourable outcomes, and reduce unnecessary patient enrolment. In the present clinical trial framework, the main performance measures considered are the operating characteristic function, average outgoing quality, average outgoing quality limit, and expected number of patients enrolled.

Operating Characteristic Function

The operating characteristic function is the primary measure used to evaluate the discriminatory ability of the proposed Bayesian SkSP–V. It represents the probability of accepting or continuing a treatment for different values of the true failure probability q. Since the treatment success probability is defined as $\mu = 1 - q$, the OC function can also be interpreted in terms of the true success probability of the treatment.

For the proposed Bayesian SkSP–V, the probability of acceptance is given by

$$P_a^{SkSP-V}(q) = \frac{P_A^B}{1 - f P_A^B},$$

where P_A^B denotes the Bayesian probability of acceptance under the reference sampling plan and f denotes the skipping fraction. The Bayesian probability of acceptance is obtained from the beta-binomial predictive distribution as

$$P_A^B = \sum_{x=0}^{i} \binom{n}{x} \frac{B(a + x, b + n - x)}{B(a, b)}.$$

Therefore, the operating characteristic function of the proposed Bayesian SkSP–V is expressed as

$$OC(q) = P_a^{SkSP-V}(q) = \frac{\sum_{x=0}^{i} \binom{n}{x} \frac{B(a + x, b + n - x)}{B(a, b)}}{1 - f \sum_{x=0}^{i} \binom{n}{x} \frac{B(a + x, b + n - x)}{B(a, b)}}.$$

A desirable OC curve should show a high acceptance probability when the treatment is effective and a low acceptance probability when the treatment is ineffective. In the present study, the acceptable failure probability is fixed at $q_A = 0.15$, which corresponds to a treatment success probability of $\mu_A = 0.85$. Similarly, the limiting failure probability is fixed at $q_L = 0.30$, which corresponds to a treatment success probability of $\mu_L = 0.70$. Therefore, the selected Bayesian SkSP–V should satisfy

$$P_a^{SkSP-V}(q_A) \geq 0.95$$

and

$$P_a^{SkSP-V}(q_L) \leq 0.10.$$

These two inequalities ensure that the proposed plan has a high probability of accepting an effective treatment while maintaining a low probability of accepting an ineffective treatment. Thus, the OC function provides a direct assessment of both producer's risk and consumer's risk in the clinical trial setting.

Average Outgoing Quality and Average Outgoing Quality Limit

The average outgoing quality is used to measure the expected proportion of unfavourable outcomes among accepted patient cohorts. In the clinical context, AOQ represents the expected failure burden after applying the proposed monitoring rule. Therefore, it is an important measure for assessing patient-risk protection. For the proposed Bayesian SkSP–V, the AOQ is defined as

$$AOQ(q) = q P_a^{SkSP-V}(q) \left(1 - \frac{n}{N}\right),$$

where Ndenotes the maximum number of patients or the notional trial size. Substituting the acceptance probability of the Bayesian SkSP–V, the AOQ becomes

$$AOQ(q) = q \left[\frac{P_A^B}{1 - f P_A^B}\right] \left(1 - \frac{n}{N}\right).$$

The average outgoing quality limit is the maximum value of the AOQ curve over the possible range of failure probabilities. It is given by

$$AOQL = \max_{0<q<1} AOQ(q).$$

The AOQL is an important patient-protection measure because it represents the worst-case expected proportion of unfavourable outcomes among accepted cohorts. A lower AOQL indicates that the proposed plan provides stronger protection against the continuation or acceptance of ineffective treatments. Therefore, in clinical trial monitoring, a plan with a smaller AOQL is preferred.

Expected Number of Patients Enrolled

The expected number of patients enrolled is used to evaluate the efficiency of the proposed Bayesian SkSP–V. In conventional fixed-sample designs, the number of patients is usually predetermined and does not change according to accumulating evidence. However, in the proposed Bayesian SkSP–V, the expected number of patients can be reduced through the skipping mechanism when the treatment shows strong evidence of efficacy.

The expected number of patients enrolled under the proposed plan is defined as

$$EN(q) = n[1 - fP_a^{SkSP-V}(q)].$$

Substituting the Bayesian SkSP–V acceptance probability, this can be written as

$$EN(q) = n\left[1 - f\left(\frac{P_A^B}{1 - fP_A^B}\right)\right].$$

A lower value of $EN(q)$indicates that fewer patients are required on average to reach a monitoring decision. This is ethically meaningful because unnecessary patient exposure is reduced when sufficient evidence is available to support treatment continuation or stopping. Thus, the expected number serves as an efficiency measure as well as an ethical indicator in the proposed clinical monitoring framework.

Parameter Selection Criteria

The selection of the parameters n, i, k, f, and $s$is carried out by considering both statistical and ethical requirements. The parameter $n$represents the cohort size, $i$represents the acceptance number, $k$represents the rejection number, $f$represents the skipping fraction, and $s$represents the deferred-state parameter. These parameters are selected in such a way that the proposed plan satisfies the producer's and consumer's risk conditions while minimizing the expected number of enrolled patients.

The optimal parameter selection problem can be expressed as

$$\min_{n,i,k,f,s} EN(q)$$

subject to

$$P_a^{SkSP-V}(q_A) \geq 1 - \alpha,$$
$$P_a^{SkSP-V}(q_L) \leq \beta,$$
$$0 \leq i < k \leq n,$$
$$0 < f < 1,$$

In this formulation, Sdenotes the maximum allowable number of deferred cohorts. A candidate plan is considered acceptable only if it satisfies the risk constraints at both the acceptable and limiting failure probabilities. Among all acceptable candidate plans, the plan with the lowest expected number of enrolled patients is selected as the optimal Bayesian SkSP–V.

Numerical Illustration and Results

To demonstrate the practical applicability of the proposed Bayesian Skip-Lot Sampling Plan V, a numerical illustration is carried out in the context of a Phase II clinical trial. The trial is assumed to involve binary patient outcomes, where each patient is classified as having either a favourable or an unfavourable clinical response. An unfavourable outcome may represent treatment failure, non-response, disease progression, or any adverse binary endpoint specified in the study protocol.

In the present illustration, the acceptable failure probability is fixed at $q_A = 0.15$, which corresponds to a treatment success probability of $\mu_A = 0.85$. The limiting failure probability is fixed at $q_L = 0.30$, which corresponds to a treatment success probability of $\mu_L = 0.70$. The producer's risk and consumer's risk are fixed at $\alpha = 0.05$and $\beta = 0.10$, respectively. Hence, the selected Bayesian SkSP–V should provide a probability of acceptance of at least 0.95 at $q_A = 0.15$and at most 0.10 at $q_L = 0.30$. For the numerical illustration, the selected design parameters are presented in Table 2.

Table 2: Selected design parameters for the Bayesian SkSP–V

Parameter	Description	Selected value
(n)	Cohort size	25
(i)	Acceptance number	3
(k)	Rejection number	7
(f)	Skipping fraction	0.6
(s)	Deferred-state parameter	2
(N)	Maximum/notional trial size	100
(q_A)	Acceptable failure probability	0.15
(q_L)	Limiting failure probability	0.3
α	Producer's risk	0.05
β	Consumer's risk	0.1

The selected values are used to evaluate the operating characteristic function, average outgoing quality, average outgoing quality limit, and expected number of patients enrolled. The probability of acceptance is computed for different values of the failure probability q. The corresponding treatment success probability is obtained using $\mu = 1 - q$.

Operating Characteristic Values

The operating characteristic values of the proposed Bayesian SkSP–V are presented in Table 3. The OC values show how the probability of accepting or continuing the treatment changes as the true failure probability increases.

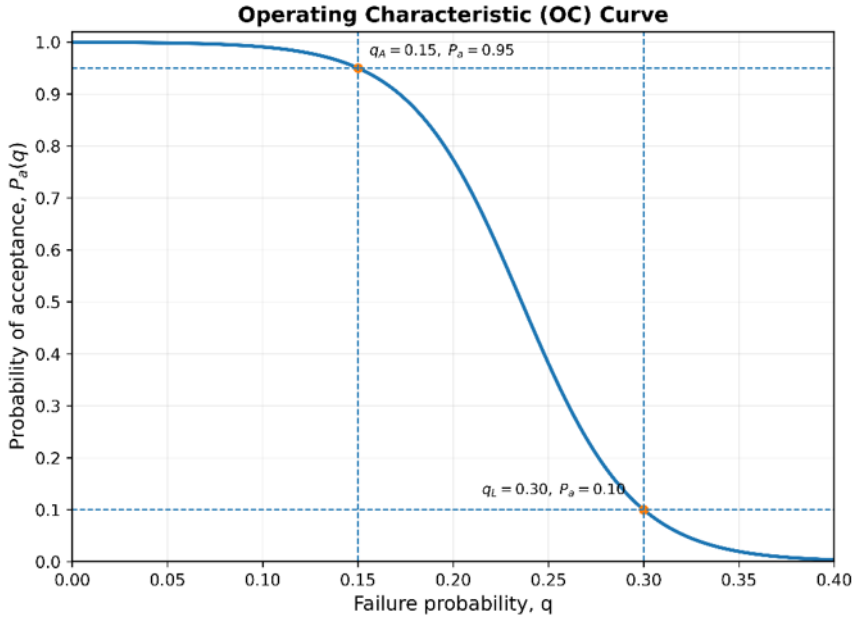
Table 3: Operating characteristic values of the Bayesian SkSP–V

Failure probability (q)	Success probability ($\mu = 1 - q$)	$P_a^{SkSP-V}(q)$
0	1	1
0.05	0.95	0.995
0.1	0.9	0.982
0.15	0.85	0.953
0.2	0.8	0.762
0.25	0.75	0.356
0.3	0.7	0.094
0.35	0.65	0.028
0.4	0.6	0.008

The results in Table 3 show that the probability of acceptance decreases as the failure probability increases. At the acceptable failure probability $q_A = 0.15$, the acceptance probability is 0.953, which satisfies the required condition $P_a^{SkSP-V}(q_A) \geq 0.95$. At the limiting failure probability $q_L = 0.30$, the acceptance probability is 0.094, which satisfies the required condition $P_a^{SkSP-V}(q_L) \leq 0.10$. Therefore, the proposed plan provides adequate protection at both the

acceptable and limiting quality levels. The OC curve corresponding to Table 3 should be presented as Figure 2.

Figure 2: Operating characteristic curve of the Bayesian SkSP–V



The OC curve is expected to show a decreasing pattern. This indicates that the proposed plan has a high probability of accepting an effective treatment and a low probability of accepting an ineffective treatment. Such behaviour is desirable in clinical trial monitoring because it supports promising treatments while protecting patients from inferior treatments.

Average Outgoing Quality Values

The average outgoing quality values are computed using

$$AOQ(q) = qP_a^{SkSP-V}(q)\left(1-\frac{n}{N}\right).$$

For the present illustration, $n = 25$and $N = 100$. Therefore,

$$1-\frac{n}{N} = 1-\frac{25}{100} = 0.75.$$

Table 4: Average outgoing quality values of the Bayesian SkSP–V

Failure probability (q)	$P_a^{SkSP-V}(q)$	$AOQ(q)$
0	1	0
0.05	0.995	0.0373
0.1	0.982	0.0737
0.15	0.953	0.1072
0.2	0.762	0.1143
0.25	0.356	0.0668
0.3	0.094	0.0212
0.35	0.028	0.0074
0.4	0.008	0.0024

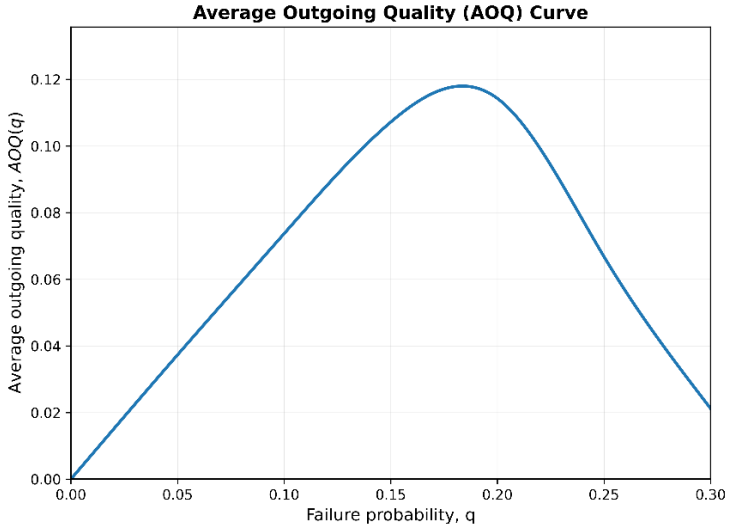
From Table 4, the AOQ initially increases as the failure probability increases. However, after reaching a maximum point, the AOQ decreases because the probability of accepting the treatment becomes very small at higher failure probabilities. This is a desirable property of the proposed plan, since poor-performing treatments are less likely to be accepted.

The maximum value of AOQ is observed as

$$AOQL = 0.1143.$$

Thus, the average outgoing quality limit of the proposed plan is 0.1143. This value represents the maximum expected proportion of unfavourable outcomes among accepted cohorts under the proposed Bayesian SkSP–V. The AOQ curve corresponding to Table 4 should be presented as Figure 3.

Figure 3: Average outgoing quality curve of the Bayesian SkSP–V



The AOQ curve provides a useful measure of patient-risk control. A lower AOQL indicates that the proposed plan limits the worst-case expected failure burden among accepted cohorts. Therefore, the obtained AOQL supports the suitability of the Bayesian SkSP–V for clinical monitoring.

Expected Number of Patients Enrolled

The expected number of patients enrolled is computed using

$$EN(q) = n[1 - fP_a^{SkSP-V}(q)].$$

For the present illustration, $n = 25$and $f = 0.60$. The EN values are presented in Table 5.

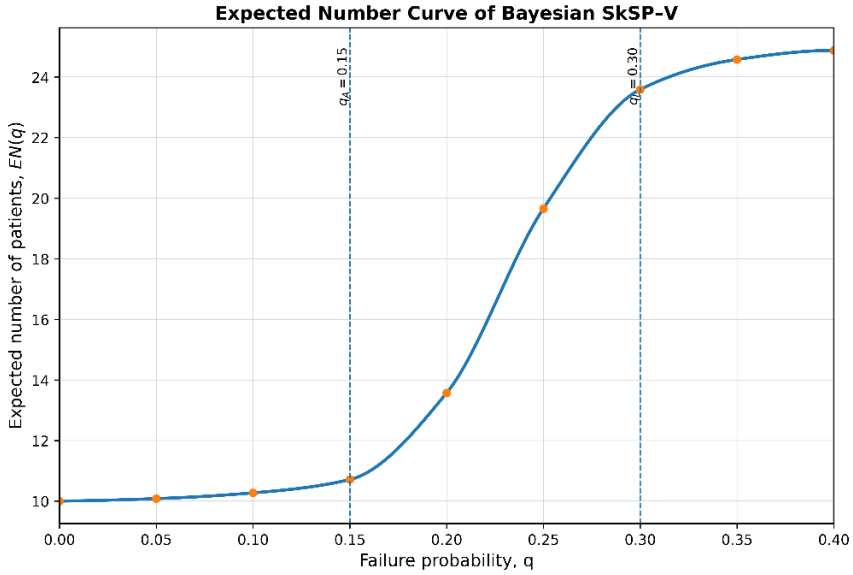
Table 5: Expected number of patients enrolled under the Bayesian SkSP–V

Failure probability (q)	$P_a^{SkSP-V}(q)$	$EN(q)$
0	1	10
0.05	0.995	10.08
0.1	0.982	10.27
0.15	0.953	10.71
0.2	0.762	13.57
0.25	0.356	19.66
0.3	0.094	23.59
0.35	0.028	24.58
0.4	0.008	24.88

The results in Table 5 show that the expected number of patients is smaller when the treatment has a low failure probability. This occurs because the proposed Bayesian SkSP–V enters the skipping mode when the treatment demonstrates strong evidence of efficacy. As the

failure probability increases, the probability of acceptance decreases and the expected number of patients approaches the full cohort size. This behaviour is clinically reasonable because treatments with weaker evidence require closer monitoring. The EN curve corresponding to Table 5 should be presented as Figure 4.

Figure 4: Expected number of patients enrolled under the Bayesian SkSP–V



The EN curve demonstrates the efficiency of the proposed plan. A lower expected number of patients indicates that the design can reduce unnecessary enrolment when sufficient evidence of treatment efficacy is observed. This provides an ethical advantage in clinical trial monitoring.

Summary of Numerical Results

The numerical results show that the proposed Bayesian SkSP–V satisfies the required risk conditions at both the acceptable and limiting failure probabilities. At $q_A = 0.15$, the probability of acceptance is 0.953, which is greater than the required value of 0.95. At $q_L = 0.30$, the probability of acceptance is 0.094, which is less than the required value of 0.10. Hence, the proposed plan provides strong discrimination between effective and ineffective treatments.

The AOQ values indicate that the proposed plan controls the expected proportion of unfavourable outcomes among accepted cohorts. The maximum AOQ value is identified as $AOQL = 0.1143$, which represents the worst-case expected outgoing failure level. The EN values further show that the proposed plan reduces patient enrolment when the treatment is performing well. Therefore, the numerical illustration confirms that the proposed Bayesian SkSP–V achieves a balance between statistical efficiency and patient protection. Overall, the results demonstrate that the proposed Bayesian SkSP–V is suitable for adaptive clinical trial monitoring. It provides a high probability of accepting effective treatments, a low probability of accepting ineffective treatments, controlled patient-risk exposure through AOQ and AOQL, and reduced expected enrolment through the skipping mechanism.

Discussion

The proposed Bayesian SkSP–V provides an efficient adaptive framework for clinical trial monitoring by combining Bayesian updating with skip-lot decision logic. The OC results indicate that the plan has good discriminatory ability, with a high probability of accepting effective treatments and a low probability of accepting ineffective treatments. This supports both statistical reliability and patient safety. The AOQ and AOQL results show that the proposed plan controls the expected proportion of unfavourable outcomes among accepted cohorts. This is important in clinical applications, where reducing patient risk is a major concern. The EN results further indicate that the skipping mechanism helps reduce unnecessary patient enrolment when sufficient evidence of treatment efficacy is available.

The deferred-state mechanism also strengthens the decision process by allowing additional evidence to be collected when the initial cohort outcome is inconclusive. Thus, the proposed Bayesian SkSP–V balances ethical protection, statistical accuracy, and operational efficiency. Overall, the plan offers a useful bridge between industrial acceptance sampling and adaptive clinical trial monitoring.

Conclusion

This study developed a Bayesian Skip-Lot Sampling Plan V for clinical trial monitoring. The proposed plan treats patient cohorts as lots and unfavourable clinical outcomes as defectives. By using a binomial likelihood, beta prior, and posterior updating, the plan provides a structured Bayesian framework for treatment monitoring. The numerical results show that the proposed Bayesian SkSP–V satisfies the required risk conditions at the acceptable and limiting failure levels. The OC curve confirms strong treatment-discrimination ability, while the AOQ, AOQL, and EN measures show effective patient-risk control and reduced expected enrolment.

Therefore, the proposed Bayesian SkSP–V offers an efficient and ethically favourable alternative for adaptive clinical trial monitoring. Future work may extend this framework to multi-arm trials, survival endpoints, dose-finding studies, and real-world clinical data applications. Future work may extend the proposed Bayesian SkSP–V framework to multi-arm clinical trials, survival endpoints, and dose-finding studies. Further studies may also validate the model using real-world clinical trial datasets and alternative Bayesian prior structures.

How to cite

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